POLICY STATEMENT on GLAUCOMA DRAINAGE DEVICES and new GLAUCOMA PROCEDURES

SOUTH AFRICAN GLAUCOMA SOCIETY

There has been a plethora of new glaucoma drainage devices on the World and South African market which has caused some confusion amongst medical personal and medical funders. This is a proposed guideline from the South African Glaucoma Society to clarify the situation.
The subject is complex and detailed and for clarity and brevity it will be presented in bullet form.

Background

1. **Glaucoma is not ONE disease. Glaucoma is a generic term for a group of complex diseases**.
   There are many types of glaucoma including Chronic Open Angle, Acute Narrow Angle, Chronic Narrow Angle, Pigmentary , PseudoExfoliation, Angle Recession, Rubeotic, Uveitic, Post traumatic to name the more common. Each type of glaucoma is treated in a different but often overlapping approach and there is a marked individual response to therapy

   KEY POINT: The complexity and variability can make it difficult for non-Ophthalmologists to appreciate the multiple approaches to treatment

2. **Glaucoma is a difficult disease to treat and despite recent advances no single ideal method or treatment has been devised.**
   Despite significant advances in recent years glaucoma is still a problematic disease with highly variable response and outcomes to current therapy. Hence multiple new treatments are still being developed and new methods explored.

   KEY POINT: There is not ONE FINAL solution for glaucoma. Treatment modalities need to be under constant review and change as glaucoma surgery does not have the predictability and safety profile of cataract, refractive and retinal detachment surgery.

3. **Glaucoma in Africa is a more aggressive disease**.[1,2,3,4,5,6,7]
   Indigenous African patients have a more **aggressive form of Chronic Open Angle Glaucoma** as well as **more aggressive scarring response** often resulting in a need for more extensive and invasive treatment.

   KEY POINT: South African surgeons are and have been early adopters of newer surgical techniques owing to the more difficult glaucoma's they have to treat.

4. **The new Drainage Devices are aimed at being minimally invasive and to have a HIGHER SAFETY profile.** [8,9]
   Glaucoma surgery has a significant complication rate which can impact on vision as well as a variable long term success rate. The newer devices are significantly less invasive and have less potential of vision impairment from the earlier procedures

Drainage Devices

1. **South Africa has a long history of Glaucoma drainage devices.**
   A South African Ophthalmologist, Dr Anthony Molteno (BJO 1969) was one of the earliest pioneers in the use of glaucoma drainage devices. Other South Africans such as Dr George Baerveldt have also developed devices. This was in response to the difficult types of glaucoma being managed and because the treatment methods available were not completely successful. Much of the early experience of glaucoma devices was developed in South Africa.

   KEY POINT: Glaucoma drainage devices are not new devices, have been extensively used for many years and South Africa has extensive experience with these already.

2. **New engineering and new concepts are producing multiple new approaches**
   Better understanding of the pathophysiology of glaucoma as well as many more doctors working on the concepts and treatment of glaucoma has produced many new approaches and new methodologies to treat glaucoma. The new advanced engineering capabilities have also produced the ability to produce smaller and better engineered devices to standards not possible in the past. The surgical routes now are directed at multiple sites: directly into the trabecular meshwork, directly into the suprachoroidal space, ab interno into the sub conjunctival space, ab externo into the trabecular meshwork and several other routes. Each new avenue has protagonists and doctors pursuing that avenue of treatment.

   KEY POINT: Recent advances in medicine and engineering have combined to produce a surge in new developments and products.

3. **Funders alarmed by the UPSURGE in use of new devices.**
   Ophthalmologists have a large pool of patients currently on medical therapy. In all parts of the world including 1st world counties compliance is a major issue [10]. In less developed countries lack of availability of medications combined with local issues such as transport compound the problems of patient compliance even further.

   So why do Ophthalmologists not operate on all glaucoma cases?

   If we had a near 100% safe and reliable procedure we would.

   However we do not have a near perfect surgical correction (unlike cataract, refractive and retinal detachment surgery) for glaucoma

   The newer drainage devices are aiming at ***INCREASED SAFETY***. When a new product becomes available Ophthalmologists have a large pool of patients with glaucoma many of them on the border or limit of requiring surgery but the doctor is withholding surgery as he is concerned about the risks of visual loss from the surgery. The newer devices have lower risk of vision loss.

Funders will note that ***when a new device becomes available there is a surge in the uptake*** of these new devices as Ophthalmologists use them in order to treat patients in a safer manner. Individual experience determines the future continued use of the device by surgeons.

This rapid adoption of new devices has happened before. This sudden increase in procedures and devices *was experienced by the funders previously* when intra ocular lenses became available many years ago. Many different types and designs became available and there was a large increase in demands on funders to pay for these devices which today are standard.

4. **Which device or method is best?**
   Progress is not linear. At times and this is one of them, there is a quantum leap in development and multiple new methods become available simultaneously. It is not possible to know which will be the best and final choice. In fact like all developments these very devices themselves will be modified and changed and will not be the "final" products, but one or several of them will be the basis of the end products. It is not possible to know now as it is only by using the various options that surgeons will settle on the most successful device.

   KEY POINT: Ophthalmologists will determine which technique and product/s will be viable by being an integral part of the decision and use and experience will be critical in this process. The South African Surgeons must use and experience these products.

5. **Which Device/s should the funders pay?**
   Funders cannot make the differentiation between the various devices and techniques as this is a surgical decision and can only be done by the Ophthalmologists. Each product will have protagonists and past experience and individual skills and training will determine each surgeons preferred method.

   The **SOUTH AFRICAN GLAUCOMA SOCIETY (SAGS)** endorses that all devices must be FDA and /or CE approved before being allowed to be used in South Africa and covered by funders. If a product is FDA/CE approved, then SAGS does NOT consider it necessary for South African Health Authorities and Providers to re-evaluate the product as the medical safety and product standards have already been established. SAGS considers that re-evaluation would be a waste of local resources and produce unnecessary delays.
   All the devices listed below have either FDA or CE approval or both. They have all already undergone multiple trials before release for surgeons to use. They are all approved devices and patient safety has been tested and confirmed.
   They still need to be used in the day to day clinical setting to ascertain their efficacy and long term viability

6. **SAGS has produced a list of current Glaucoma drainage devices presently available both in South Africa and internationally which will/may become available locally.As these are all FDA/CE approved SAGS considers them appropriate to use under the correct medical indications.**
   Please see attached document providing further details on available devices which are certified for use by the FDA and CE board. New products and many modifications will be made to current products in the future as development occurs.

KEY POINT: This document provides a list of the currently available devices that the South African Glaucoma Society accepts as FDA and/or CE approved products which have passed safety and product standard testing and can be allowed for use by South African Surgeons after appropriate training of the surgeon and the correct selection of patients for the surgical method.

7. **Funding difficulties**
   SAGS appreciates the difficulty funders find in deciding what to fund , how much and when. Funders already have device protocols in place for Glaucoma devices eg Molteno , Ahmed and Baerveldt devices have been used for many years in South Africa. This should continue to be the basis for use of all these devices.

   We appreciate that the recent increase in use of the devices has had a significant impact on finances and wish to draw to their attention that as these devices become better more will be used and that funders must plan for this increase in use and costs just as they did with intra ocular lenses.

   The reduced spend on intraocular pressure lowering agents with surgically controlled glaucoma is a further important aspect to consider in cost calculations.

   KEY POINT: Funders must plan for the increase use of glaucoma drainage devices in the management of glaucoma and **actuarial analysis of this future need is required** now for planning purposes.

8. **SAGS is willing to act in an advisory capacity when funders are approached with non-standard requests**
   Funders are sometimes presented with requests that are not in line with the average request received for glaucoma procedures. SAGS is willing to act in a consultative process and understands the need for accessible and rapid decision making in this regard. We will provide a contact/s who the funder can telephone to discuss the problem and a guideline or suggested action will be given to the funder.

   KEY POINT: The Glaucoma society understands the difficulty and complexity faced by the funders and that it requires a consultative on going case by case process to develop a working protocol that provides a workable solution.

See below for table documenting glaucoma drainage devices, lasers and other methods currently available

	How it works	Indications	Advantages/Disadvanges	Complications	Contra-indications	Administrative
Glaucoma setons **Molteno** Implant First Second Third Generation: biological **Ahmed** valve **Baerveldt** Implant	A glaucoma seton is a medical shunt used in the treatment of glaucoma to reduce the eye's intraocular pressure (IOP).	These are indicated for glaucoma patients not responding to maximal medical therapy, with previous failed guarded filtering surgery (trabeculectomy). Refractory glaucoma Neovascular glaucoma Uveitic glaucoma Juvenile glaucoma Silicone glaucoma	Good Pressure reduction Can be used with refractory Glaucomas Neovascular glaucoma	Hypotony and IOP rise Choroidal detachment Diplopia Corneal oedema/ injury Iridocyclitis Vision loss Tube erosions Tube Occlusions Encapsulated bleb	Infections Conjunctival scarring	FDA approvals Molteno glaucoma implant K062252 K902489 K890598 K152996 Ahmed glaucoma implant K925636 K980657 Baerveldt Glaucoma implant K905129 K955455
Canaloplasty	Non-penetrating surgical technique that takes advantage of the eye's natural drainage network to reduce IOP in pasients with POAG	POAG Pediatric Glaucoma	Less invasive Minimal complications Lower risk for hypotony or hyphema Decrease risk of cataract formation No bleb related risks Patient able to wear contact lenses	Less reduction in IOP Steep learning curve	Neovascular glaucoma Angle dysgenesis Plateau Iris Corneal oedema or opacities Elevated episcleral venous pressure Angle Closure Glaucoma	Sterigenics International LLC FDA Approved Product class: HMX Device class: 1 Regul. No: 886.4350 Reg Establ No: 2953359 Owner no:10029425

Express Implant	Stainless steel glaucoma shunt device Inserted under a scleral flap into the anterior chamber	All patients inadequately controlled on medications of laser therapy Previously failed trabeculectomy Require shorter recovery rate	Potentially less complications than a trabeculectomy Can be combined with cataract surgery Average learning curve	Early post op hypotony Flat anterior chamber Hyphema Cataract Study: Express glaucoma filtration device: review of clinical experience and comparison with trabeculectomy		ALCON Research LTD FDA Approved K012852 Product code: KYF Device Code:2 Regul no: 886.3920 Reg Establ No: 2523835 Owner No:1610287
Trabectome	Electro-cautering of the TM allowing aqueous drainage to the collector channels. Lowering the IOP to normal episcleral venous pressure	All glaucomas paediatric glaucoma Pigment dispersion syndrome Pseudo exfoliation syndrome uveitic glaucoma	Minimal invasive Can be used in conjunction with cataract surgery Conjunctiva Spared Excellent safety profile Rapid recovery Directly improves physiological outflow Positive patient outcome	mild hyphema - 1 week Fluctuating IOP for 1 month - keep on meds Peripheral anterior synechiae need isoptp-carpine 2%	Neovascular glaucoma Angle dysgenesis Plateau Iris Corneal oedema or opacities Elevated episcleral venous pressure Angle Closure Glaucoma	Neomedix corporation FDA Approved 2004 21 CFR 878.4400 K061258 CE Approval 2003 Machine: M4558 Hand piece: DM1207844
iStent GTS100 **iStent inject** GTS400	Micro-scale stent implanted into the canal of Schlemm through the TM	Mild to moderate glaucoma Pigment dispersion syndrome Pseudo exfoliation syndrome uveitic glaucoma	Minimal invasive Can be used in conjunction with cataract surgery Conjunctiva Spared Excellent safety profile Rapid recovery Directly improves physiological outflow Positive patient outcome	Stent obstruction Corneal oedema Early post-op anterior chamber cells	Neovascular glaucoma Angle dysgenesis Plateau Iris Corneal oedema or opacities Elevated episcleral venous pressure	GLAUCOS CORP FDA Approval P080030 Product code:OGO Device Class: 3 Reg establ no: 2032546 3012833022 Owner no: 9050364

iStent Supra	Micro stent intended to be placed in the supra-cilliary space. Directing the Aqueous into the small holes and into the uveoscleral space	Open angle glaucomas POAG, PXG, PDS, Steroid induced, OHT	Direct channel between the anterior chamber and the supra-cilliary space. Stand alone procedure or combined with a cataract surgery	Temporary stent obstruction Malposition needing a secondary procedure	Angle closure glaucoma, moderate-advanced glaucoma	GLAUCOS CORP FDA Approval Product code:OGO Device Class: 3 2032546
HFDS High-frequency deep sclerotomy **HFDS® ab interno MIGS technology**	High Frequency Deep Sclerotomy ab interno creates direct access from the anterior chamber to the Schlemm's canal and further to the sclera. The resistance of the trabecular network is thus avoided. The abee® glaucoma tip is led through a paracentesis of 1.2 mm and creates six little sclerotomy pockets in the iridocorneal angle.	POAG Combining with cataract surgery	Minimal invasive Ideally combined with cataract surgery No bleb formation No corneal scars Conjunctiva Spared Good safety profile Rapid recovery Directly improves physiological outflow Positive patient outcome Procedure can be repeated	mild hyphema - 1 week Fluctuating IOP for 1 month - keep on meds Peripheral anterior synechiae	Neovascular glaucoma Angle dysgenesis Plateau Iris Corneal oedema or opacities Elevated episcleral venous pressure Angle Closure Glaucoma	CE Mark approval ABEE glaucoma tip 244057 MR2 ID 170624170 Oertli machine CE0297
Xen Glaucoma treatment system	Collagen-derived, porcine gelatin targets the sub-conjunctival space as trabeculectomy, bypasses all potential outflow obstructions to for a small bleb	Moderate glaucomas	Minimal invasive Similar to a Trabeculectomy Can be used in conjunction with cataract surgery Conjunctiva spared Excellent safety profile Rapid recovery Positive patient outcome	Hypotony lasting one day Stent obstruction Corneal oedema Early post-op anterior chamber cells Post op Needling 10 - 30 % Hyphema 3.8% APEX study	Neovascular glaucoma Angle dysgenesis Plateau Irish	ALLERGAN CE Mark approved CE 597638 FDA Procedure Product Code: KYF Device class: 2 Reg No: 886.3920 Reg Establ No: 3007851988 Owner No: 10039662 Available in SA
Cypass	Micro stent intended to be placed in the	Open angle glaucomas POAG, PXG, PDS,	Direct channel between the anterior chamber and the	Temporary stent obstruction Malposition	Angle closure glaucoma, moderate-advanced	ALCON Research LTD

	supra-cilliary space. Directing the Aqueous into the small holes and into the uveoscleral space	Steroid induced, OHT	supra-cilliary space. Stand alone procedure or combined with a cataract surgery IOP lowering of 35%	needing a secondary procedure CyCLE study	glaucoma	FDA Approval P150037 Product code: OGO Device class: 3 Reg establ no: 1610287 Owner no:1610287 Awaiting registration at the MCC in SA. Will soon be available
Canal expanders	The Stegmann Canal Expander® is the latest development in canaloplasty, and the first implantable device into Schlemm canal to treat effectively glaucoma. The Stegmann Canal Expander® is a powerful biocompatible, non-metal, non-gelatin micro-implant	POAG Paediatric Glaucoma	Less invasive Minimal complications Lower risk for hypotony or hyphema Decrease risk of cataract formation No bleb related risks Patient able to wear contact lenses	Less reduction in IOP Steep learning curve Dislocation of the expander	Neovascular glaucoma Angle dysgenesis Plateau Iris Corneal oedema or opacities Elevated episcleral venous pressure Angle Closure Glaucoma	CE Mark approval in 2012 (CE 0124) Material is FDA approved
HYDRUS Aqueous Implant	Micro stent - semi-circular tube with perforated walls, 8mm long Titanium alloy Inserted into Schlemm's canal Preventing the collapse of the SC Enhance outflow and access to the collector channels	Mild to moderate open angle glaucomas with co-existing cataract PXE,PDS,Adjunctive procedure in poly pharmacy Poor compliance	Reduce medication burden No Scarring of ocular tissues Fast recovery Disadvantages: Transient mild hyphema No major complications reported in the studies Steep Learning curve	Potential displacement Potential damage to structures Intra-ocular inflammation Studies: IOP drop 21 - 16% Drop reduction 2 - 0.4% 855 of patients rendered drop free	Angle closure glaucoma Previous Glaucoma Surgery Severe Glaucomas Mono-ocular patients	IVANTIS, INC FDA Approved Product code:OGO Device class: 3 Reg Establ No: 3007683266 Owner no: 10037330 In the Process of entering SA

InnFocus Microshunt (formerly MIDI Arrow)	drainage implant device that helps effectively drain eye fluid and reduces intraocular pressure that will prevent the progression of glaucoma and vision loss.he drainage implant consists of an extremely small micro-tube (about twice the size of an eyelash) that shunts aqueous fluid from the anterior chamber of the eye to a sub-conjunctival/sub-Tenon flap. The shunt was designed to be thin and soft to conform to the curvature of the eye.	POAG	The implantation time is shorter Easy to perform An alternative to tube or trabeculectomy procedures.	Bleb related complications	Risk for infections and bleeding	InnFocus Inc FDA Approved Product code: KYF Device Class: 2 Regul No: 886.3920 Reg Establ no: 3011035920 Owner no: 10047248 InnFocus developed the Microshunt™ (formerly known as MIDI Arrow) with the University of Miami's Bascom Palmer Eye Institute (one of the leading ophthalmology institutes in the world).
Solx Gold Shunt	24 k Gold Micro stent implant Connecting the anterior chamber - above the scleral spur - supra-choroidal space 20-50% increase in uveoscleral outflow	Refractory Glaucomas	No Bleb related complications High biocompatible Reproductive procedure Disadvantages: Unpredictable long term IOP control Large Foreign body in the supra-choroidal space Conjunctival peritomy and scleral dissection (learning curve)	Vision blurred for 2 weeks IOP - hypotony Choroidal detachment corneal oedema Exudative retina detachment Implant migration or exposure Iris touch Corneal touch Hyphema Inflammation Studies: Phase III randomised controlled comparative FDA trial	Infection Possible Vision loss Uveitic glaucomas need to be carefully chosen	European certified CE 0473 Will soon be introduced to SA

STARFlo	STARflo is a permanent implant which is surgically inserted suprachoroidally to facilitate draining of aqueous from the eye without tissue fibrosis, bleb formation and ideally without the use of anti fibrotic drugs.	A Prospective, Non-comparative, Multi-center Clinical Trial to Evaluate the Safety and Efficacy of the STARflo Glaucoma Implant in Patients With Open Angle Glaucoma is underway.	POAG not controlling on medications	Reduction in IOP comparative to other methods.	Allergic reations to materials Other forms of glaucoma Still awaiting long term data	IStar Medical CE mark approved 2012 Soon to be introduced into south Africa
Aquashunt	Blebless ab-externo glaucoma surgery. Polypropylene suprachoroidal drainage device. Connecting the anterior chamber - above the scleral spur to the supra-choroidal space. 20-50% increase in uveoscleral outflow	Refractory Glaucomas	No Bleb related complications High biocompatible Reproductive procedure Disadvantages: Unpredictable long term IOP control Large Foreign body in the supra-choroidal space Conjunctival peritomy and scleral dissection (learning curve)	Limited date with only the Phase I information available 80% *IOP* lowering 1 month post op - < 10 mmHg. At 6 months > 20% reduction in IOP	Still await long term data for efficacy and safety. Well tolerated with few adverse events	OPKO Health Inc.
AquaFlow Collagen Glaucoma Drainage Device Model CGDD-20-P000026	Device to maintain a space under the sclera (supra-choroidal). Once placed it swells and absorbs fluid. This reduces the IOP. It dissolves in 6-9 months, creating the space for drainage	POAG not controlled on medications	IOP reduction is comparative to other invasive forms of surgery Reduces the number of glaucoma medications	Iridocyclitis Foreign body – sensation and bulky	Allergic reactions to collagen products Other types of glaucoma Glaucoma that can control with medicine.	STAAR Surgical CO FDA approved in 2001 P000026

Trans scleral Photocoagulation	Photocoagulation of the sclera decreases the production of fluid in the eye, and leads to decreased eye pressure.	Intractable Glaucoma Elevated IOP with poor visual potential Pain relief in blind eye Uncontrolled glaucoma Medically not suited for surgery All kinds of glaucoma	IOP reduction in refractory glaucoma Non-invasive	Pain Iridocyclitis Conjunctival burn Hypotony Vision loss Phthisis bulbi	Glaucoma with good vision	
Endo-Cyclo Photocoagulation	Selective destruction of the ciliary body to treat glaucoma ECP, a miniature endoscopic camera is placed inside the eye to view the cilliary processes that produces the fluid inside the eye. This area is then directly treated with a laser which decreases the production of fluid in the eye, and leads to decreased eye pressure.	Refractory Glaucoma	Safe Minimal invasive Several studies have shown that after treatment, most patients reduced or even eliminated their need to take eye drops. ECP can be combined with cataract surgery too with good success rates. Phthisis bulbi, endophthalmitis, or sympathetic ophthalmia was not found	Fibrin exudates Hyphema Cystoids edema Vision loss of 2 lines or more.	Infections Uveitic Glaucoma	

Authors: Bill Nortje & Marissa Willemse Oct 2016. Document approved by the SAGS Exco meeting Nov 2016

REFERENCES

1. Friedman DS, Wolfs RC, O'Colmain BJ, et al, Eye Diseases Prevalence Research Group. Prevalence of open-angle glaucoma among adults in the United States. Arch Ophthalmol 2004;122:532-8.

2. Vajaranant TS, Wu S, Torres M, Varma R. The changing face of primary open-angle glaucoma in the United States: demographic and geographic changes from 2011 to 2050. Am J Ophthalmol 2012;154:303-14.

3. Sommer A, Tielsch JM, Katz J, et al. Racial differences in the cause-specific prevalence of blindness in east Baltimore. N Engl J Med 1991;325:1412-7.

4. Varma R, Ying-Lai M, Francis BA, et al, Los Angeles Latino Eye Study Group. Prevalence of openangle glaucoma and ocular hypertension in Latinos: the Los Angeles Latino Eye Study. Ophthalmology 2004;111:1439-48.

5. Stein JD, Kim DS, Niziol LM, et al. Differences in rates of glaucoma among Asian Americans and other racial groups, and among various Asian ethnic groups. Ophthalmology 2011;118:1031-7.

6. Tielsch JM, Sommer A, Katz J, et al. Racial variations in the prevalence of primary open-angle glaucoma: Tthe Baltimore Eye Survey. JAMA 1991;266:369-74.

7. Leske MC, Connell AM, Schachat AP, Hyman L. The Barbados Eye Study: prevalence of open angle glaucoma. Arch Ophthalmol 1994;112:821-9.

8. Saheb H, Ahmed II. Micro-invasive glaucoma surgery: current perspectives and future directions. Curr Opin Ophthalmol. 2012 Mar;23(2):96-104. doi: 10.1097/ICU.0b013e32834ff1e7.

9. http://www.brightfocus.org/glaucoma/article/glaucoma-surgery-series-minimally-invasive-glaucoma-surgeries-migs

10. http://www.glaucoma.org.au/article-jan2009.htm