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OPHTHALMIC SURGERY PRODUCTS

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Content

GSL Glucoma
Device I & II

Conjunctival blebs heal. Subscleral space gets fibrosed. Passage & absorption of fluid in trabeculectomy is stopped, Tube shunt is blocked. These are some of the common problems faced by the Glaucoma Surgeons.

Surgiwear brings you an answer to your problems. The " GSL Glaucoma Device".

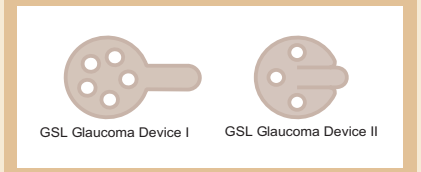
- There is no tube to get blocked.
- Healing & fibrosis can not occur through the silicone layer.
- Trabeculectomy will work for longer periods.
- Can be implanted into failed trabeculectomy
- No obliteration of conjunctival bleb.
- You will not be required to inject anti-cancer drugs into the bleb.

The GSL Glaucoma device is a very simple device. It is made of implant grade silicone elastomer. It has been cut using sophisticated machines.

Just do standard trabeculectomy. Before closure of scleral flap place lip part of it into the subscleral space & disc part of it under the conjunctiva.

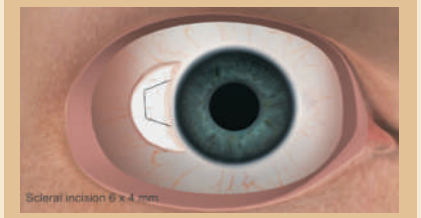
Following are the guiding steps to help you in using these devices. Same steps can be used to do SICS with trabeculectomy & implantation of GSL Glaucoma Device.
Following important points should be noted:

- First of all you need a scleral flap & bigger one, when doing SICS with GSL Glaucoma device implantation.
- Secondly the incision line of conjunctiva should not fall on the bare device.
- Incision line of conjunctiva and sclera should be away from each other.



Implantation guide lines

A conjunctival incision, 6-7 mm long 2 mm from limbus, is made. A conjunctival flap is created. Conjunctiva is dissected back. A pocket is created under the conjunctiva

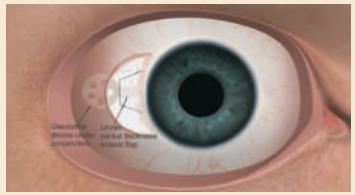


Two converging scleral incisions are made 35 - 50 microns deep, 6-8 mm apart (depending upon the size of nucleus) starting near the limbus and 4 mm long towards periphery. The peripheral ends of two incisions are 4 mm apart. A third incision joins two incisions at distal points. A partial thickness flap of sclera is created. The subscleral dissection is further advanced to enter anterior chamber.

SICS is performed through subscleral tunnel, thus created, on standard lines.

A standard trabeculectomy is performed through the scleral tunnel.

A suitable size space is created under conjunctiva & Tenon's capsule, distal to scleral incision. The pocket should be just sufficient to accommodate GSL Glaucoma device.

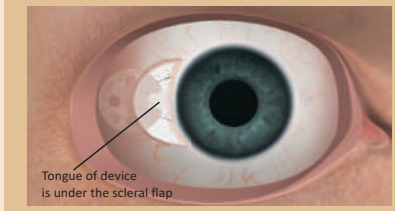


GSL Glaucoma device I is placed under the conjunctiva into the pocket created. The arm of device is placed into the scleral tunnel. The end of tongue should be just near to the trabeculectomy.

The scleral flap is closed & stitched.

The conjunctival incision is also closed with suitable sutures.

PLACEMENT OF GSL GLAUCOMA DEVICE II



GSL Glaucoma Device II is placed in similar fashion. The tongue of the device is placed under the scleral flap into the tunnel. Rest of the device remains outside under the conjunctiva. The end of the tongue is near to the trabeculectomy. The scleral flap is closed with two stitches at the two corners. The conjunctiva is sutured back.

Presentation
GSL Glaucoma Device is available double packed in peel open pack & ETO sterilized.

Type	Code no.
GSL Glaucoma Device I	GGD-1
GSL Glaucoma device II	GGD-2

Complications
Complications can be classified into following categories:
a. Complications due to the disease
b. Complications due to the operation
c. Complications due to the Implant

An implant procedure has some of its own complications. You are inserting a foreign body in to the body. It is prone to infection, expulsions and rejections. Complications associated with GSL Glaucoma device are:

* Infection.
* Migration of device.
* Swelling at the implantation site.
* Expulsion. Sometimes the device erodes through conjunctiva. These are to be dealt accordingly.

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Patents in India & International Patent pending
Design registration pending

"BP VALVE" Glucoma Shunt

i INTRODUCTION

"BP Valve" Glaucoma Shunt has been developed by SURGIWEAR in association with renowned surgeons. It is a very simple & effective device with no high sounding mechanics or valves. It has just three parts a tube, a membrane valve and a button, all made of medical grade silicone. It has following important features.

a. "BP Valve" or body pressure valve. The valve regulating the flow does not have any opening pressure of its own. It is being pressed by body's own tissues. When the pressure of fluid in eye is more than pressure of body tissues, the valve will open and allow flow of fluid. Thus the fluid pressure inside the eye is maintained at the level of body pressure.

b. "Peaks on button" there are multiple peaks on the button. These peaks keep conjunctiva and Tenon's capsule away from button to facilitate distribution of fluid around. The fluid can pass beyond the button also, because there is no limiting ridge around. Thus effectively it has large absorption area for the fluid to get absorbed back.

c. Soft and flexible button with rough upper surface. The button body is soft so easy to implant. The rough top surface creates large surface area and prevents sticking of valve with button body.

p PRESENTATION

The Glaucoma shunt is available sterilized ready to use in three sizes:

1. Regular size 2. Small size 3. Large size.

Depending upon size of the eye ball and severity of problem the size is selected.

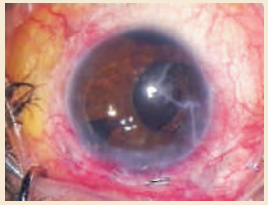
i INDICATION

Glaucoma shunt is considered as tertiary option. When routine operative measures fail, it should be considered as an option. In some complicated glaucoma cases, it may be taken as first option. It is indicated in almost all types of glaucoma such as neovascular, congenital and uveietic glaucoma.

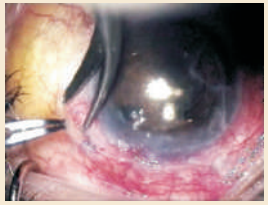
o OPERATIVE STEPS

Following are the steps of operative procedure. These steps are being narrated for guidance only. A surgeon should use operative steps dictated by his training and knowledge. It is presumed here that the surgeon is familiar with glaucoma shunts, its use and complications.

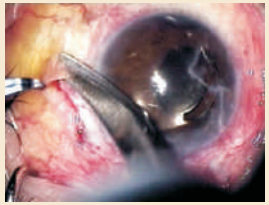
Drapes used during surgery should be lint free. First of all take out the tag inserted into the valve then flush the shunt with normal saline using 27 gauge needle. No air bubble should be left inside the tubing and patency of shunt is also checked by flushing the tube.



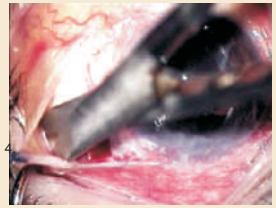
1. It is a case of uncontrolled glaucoma with multiple trabeculectomies with anterior chamber IOL



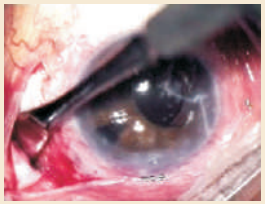
2. An incision is given in either upper outer or upper inner quadrant.



3. Conjunctiva in and Upper inner quadrant is being cut and opened up.



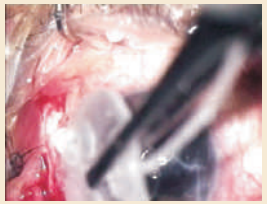
4. A pocket is created under conjunctiva & Tenon's capsule with curved corneal scissors.



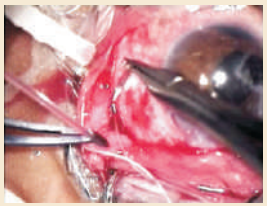
5. Curved blunt spatula is used to further clear the pocket.

6. Glaucoma Shunt is flushed with saline using 27 gauge cannula.

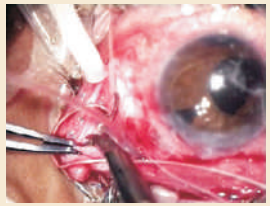
7. Patency of system is checked. Fluid should flow out freely from the valve



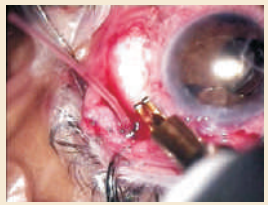
8. Glaucoma shunt is inserted into the pocket created under conjunctiva & Tenon's capsule.



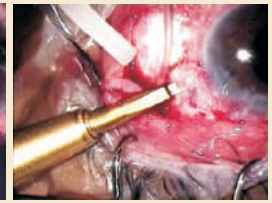
9. The valve is sutured in place using 6/0 non absorbable suture. The position of valve should be 10 mm behind limbus.



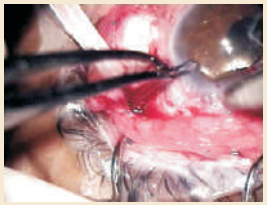
10. The needle is passed through the eyelets present in the shunt (not shown in the picture)



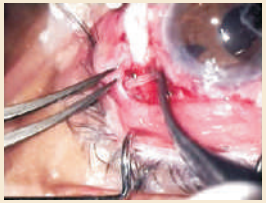
11. Graded micrometer knife is used to make two cuts 35 micron deep into sclera to burry the tube under it.



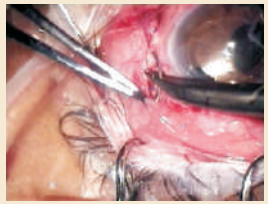
12. 1.2 mm diamond knife is used to create a passage through the sclera through the cuts. same knife is used to enter into ant. chamber



13. Length of tube is cut in an oblique fashion Length should be just sufficient to enter into the anterior chamber.



14. The tube end is pushed through the passage created. The end of tube should be visible in the anterior chamber.



15. The conjunctiva is closed using absorbable suture.

Complications

Complications can be classified into following categories:

a. Complications due to the disease

b. Complications due to the operation

c. Complications due to the Implant

An implant procedure has some of its own complications. You are inserting a foreign body in to the body. It is prone to infection, expulsions and rejections. Complications associated with shunt are infection and blockage of shunt tube. over a 12 month period 10-15% of shunt tubes may be blocked. Thesecan be opened by laser burning debris present on the tip or by flushing it. Other possible complications are migration ot tube, migration of button body and swelling around button body. These are to be dealt accordingly.

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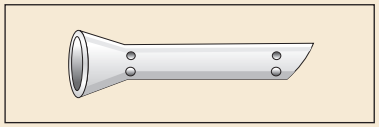
Pawar Intracystic Implant

The PAWAR intra cystic implant has been developed by Dr. M.D Pawar, an Ophthalmic surgeon from Nagpur, India, after years of research.

i INTRODUCTION

PAWAR Intra cystic Implant is a brain child of Dr. M. D. Pawar, Ophthalmic Surgeon from Nagpur. This is a new method for treatment of Epiphora due to obstruction of lacrimal passage e.g. Dacrocystitis.



The Main Aim behind the design is to make treatment of Epiphora simple, quick and effective by using this implant better success rates have been obtained. This implant can be used in cases where conventional treatment is contraindicated.

a ADVANTAGES

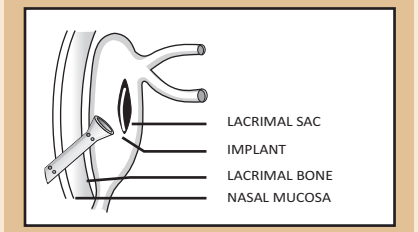
Following are important advantages of this implant over conventional treatment.

1. A technically easier and less time consuming procedure.
2. Per operative bleeding is tremendously reduced, no need for nasal packing.
3. Shorter Hospital stay & reduced post operative bleeding.
4. Can be done in all age groups. Infancy is not contraindication.

5. Deformed nasal bridge and senile atrophic mucosa are not complications.
6. Success rates in Implant DCR are better than conventional flap dacrocys-torhinostomy.
7. Implant in situ does not cause any discomfort or complication.

t THE IMPLANT

The PAWAR Intra cystic Implant is made of medical grade silicone elastomer, one of the best material suitable for Implantation. The Implant material has funnel shaped wider end protrudes in the nasal cavity.



Diagrammatic demonstration of position of the Pawar Implant after operation

Following three types of implants are available:

1. Large Implant for New Ostium
2. Large Implant for naso lacrimal duct.
3. Small implant for Conjunctiva-dacrocysto-rhinostomy operation (with both puncti are blocked)

i INDICATIONS

These are similar to conventional DCR.

c CONTRAINDICATIONS

Same type of contraindications should be considered as in conventional DCR.

h HOW SUPPLIED

The Pawar Intra cystic Implant is supplied packed in blister peel open pack, ready to use and sterilized by ethylene oxide. Each pack contains one implant.

s STERILIZATION

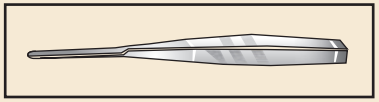
The Implant should be used once only. However if needed it can be re sterilized by autoclaving. In a clean environment and with gloved hands remove implant from its package. The package is not sterilizable. It should be rinsed with distilled water and then autoclaved by using one of the following methods:

1. High Speed autoclave for 10 minutes at 131̊ C (2 kg/cm2)
2. Standard autoclave for 30 minutes at 121̊ C (2 kg/cm2)

s SPECIAL INSTRUMENTS

FOR FASHIONING OF NEW OSTIUM

a) Jenkins type Mastoid gauge 2.5mm or 3 mm in size. It can be bought from any surgical dealer. It is a common instrument used in ENT.



Jenkins type mastoid gouge

b) Blunt lacrimal sac dissector can also be used to create a new ostium. Be careful about the size.

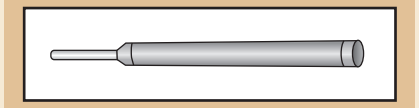
Blunt lacrimal sac dissector

Special perforator from Surgiwear

c) Special perforator has been developed by Surgiwear. It is available in two sizes, Large and Small.

FOR INTRODUCING THE IMPLANT

Special Introducer has been developed by Surgiwear. It is available in two sizes, Large and Small.



Special Introducer from Surgiwear

o OPERATIVE PROCEDURE

Position of patient and anaesthesia are similar to as used in conventional DCR.

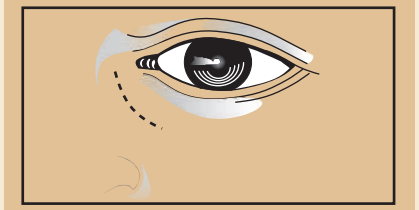
INCISION AND EXPOSURE

Exposure of sac is carried out exactly as that for conventional DCR.

Following procedure is suggested for inserting the implant into a new ostium.

INCISION IN THE LACRIMAL SAC

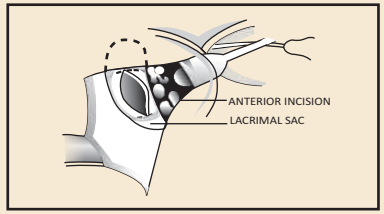
A vertical incision around 3 mm long is made in the anterior wall of the lacrimal sac.



Skin Incision

FASHIONING THE OSTIUM

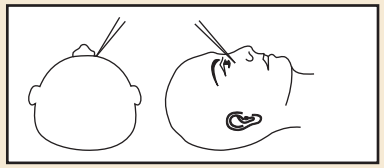
The ostium is created by using any of the instruments described above, in the lower part of the lacrimal fossa. The instrument passes through the posterior wall of the lacrimal sac, lacrimal bone and nasal



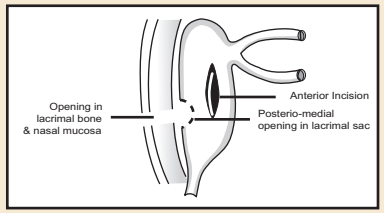
Invision in the lacrimal sac

mucosa. The instrument points towards posterior, medical and lower direction as shown here.

i IMPLANTATION

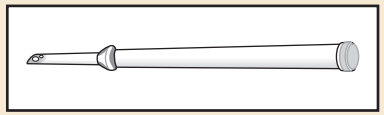


Direction of perforating instrument



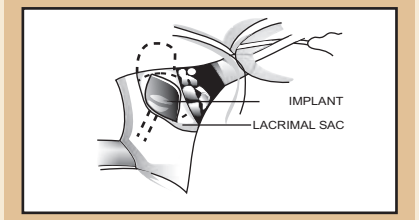
Diagrammatic presentation of Incision & New Ostium

A sterilized implant is loaded on the introducer as shown here.



The Pawar Implant loaded on the Introducer

Now the implant is introduced through the anterior opening of the lacrimal sac in to the nasal cavity negotiating the posteriomedial wall of the lacrimal sac and newly fashioned ostium. It is placed in such a way that it



The position of Pawar Implant after insertion

points towards posterior, medial and lower directions similar to the direction of mastoid gouge. The wider portion (collar) lies in the cavity of the sac and the other end in the middle meatus or lower meatus of the nose.

Operative procedure for inserting the implant into the Nasolacrimal duct

Up to the exposure of the lacrimal sac and anterior incision in the wall of the lacrimal sac, the procedure is the same. The Nasolacrimal duct is dilated by using suitable dilators. The implant is loaded into the dilated naso-lacrimal duct.

POSITION CHECK OF THE IMPLANT

Saline is injected through the funnel of the implant. Observe air bubbles from the nostril via The Implant. The position of the implant should be confirmed visually also by inspecting the nostril by using nasal speculum. The pointed portion of the implant should project in the nasal cavity.

CLOSURE AND PATENCY CHECK AFTER CLOSURE

The sac and surgical field is irrigated with normal saline and 1:1000 adrenalin. The wound is closed with 6/0 chromic catgut in layers. The function of implant may be tested immediately after the closure on table itself. The punctum is dilated and syringing is performed.

MEDICATION AND POST OPERATIVE CARE

Patient is kept on oral antibiotic and anti inflammatory drugs for 3 days. Topical antibiotic drops are instilled for the period of one month. De congestive nasal drops are used

in the nostril of operated side four to six times in a day for one week.

First syringing is done on the third day and repeated once a week for four weeks.

i COMPLICATIONS

The main post operative complications are blockage of implant and infection.

Blockage in immediate post operative phase is mostly due to clot or improper insertion of implant through the mucosa. Sometimes the implant does not pass through the nasal mucosa and nasal tenting occurs. On table tests may show correct procedure but as the mucosa heals the implant is blocked. During operation, bleeding points should be taken care of. Wound, during operation, may be irrigated with 1:1000 adrenalin.

Late blockage of nasal passage via implant is due to infection and granulation tissue formation in 2% of the cases. Persistent infection may warrant removal of device.

b BIBLIOGRAPHY

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Solid Silicone Eye Sphere

i INTRODUCTION

Every human being deserves good look. After evisceration the sclera and muscles contract and shrink. The contour of eye is lost. The artificial eye prosthesis, worn later on, will always look artificial due to lack of eye movements. If evisceration has been done in childhood the eye socket may not develop to full size and a bony deformity may occur.

The purpose of solid silicone eye sphere is to maintain contour of eyeball, maintain the eye movements, provide a base for prosthesis, and maintain shape of eye socket and to prevent bony deformity. Lastly, but not the least, to give full self-confidence to the patient.

It gives excellent cosmetic results. The artificial eye prosthesis, to be worn later on, will look natural due to good eye contour and almost full eye movements.

d DESCRIPTION OF EYE SPHERE

The solid eye sphere is made of medical grade silicone elastomer. It is molded in one piece. It is supplied in peel open packs, ready to use, sterilized by ethylene oxide. Each packet contains one eye sphere. The solid eye sphere is for single use only It is available in four sizes:

SIZE	CODE NO.
14 mm	ES14
16 mm	ES16
18 mm	ES18
20 mm	ES20.

i INDICATIONS

Solid eye sphere is indicated in all cases where evisceration is done and good cosmetic results are desirable. It can also be used in cases of enucleation where an 11 mm rim of sclera with muscles attached has been left.

c CONTRAINDICATIONS

Like all implants, it is contraindicated in cases where active infection or inflammation is present. Preferably it should be inserted after six months to one year of subsidence of inflammation.

p PRECAUTIONS

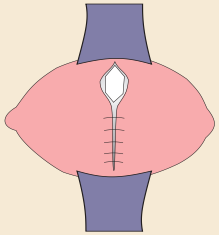
Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

o OPERATIVE PROCEDURE

The implantation of silicone eye sphere may be accomplished through variety of procedures. The choice depends upon the training of surgeon, customs in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient. Following procedure is to act as guideline only.

Insertion of solid eye sphere is done after completion of evisceration of eye and before

closure of sclera and conjunctiva. Evisceration is done on standard lines. A proper size of eye sphere is selected.



The solid eye sphere is inserted into the scleral cup. The edges of sclera are sutured in a vertical line with interrupted vertical inverting mattress sutures. To avoid "dog ear" projections of sclera at each end of the sutured line, a triangle of sclera is excised from each end with the bases towards the center.

An alternative procedure is to make from the limbus four radial scleral incisions about 5 mm long at 1.30, 4.30, 7.30 and 10.30 o'clock when eye sphere is in place, two chromic catgut mattress sutures approximate the medial and lateral scleral flaps and two chromic catgut sutures join the upper and lower flaps.

Tenon's capsule is sewn over this with horizontal line of interrupted 1 metric (6/0) chromic catgut sutures and the conjunctiva with continuous key pattern suture of 0.5 metric (8/0) chromic catgut.

p POST OPERATIVE MANAGEMENT

The patient may be mobilized early. On the first postoperative day the conjunctival sac is irrigated. The firm pressure dressing is maintained for 2 days, when the socket is dressed. This may be re applied with daily dressings until the fifth day. An acrylic shell may be placed in the conjunctival sac and a convex black eye shade, lined with sheet of lint, the smooth side opposed to the socket, is applied. The acrylic shell, approximately the shape and size of prostheses to be fitted later, helps to reduce the edema of the conjunctiva and to maintain the appropriate size and shape of the socket.

A prosthesis is fitted in the third or fourth week of operation. Pain may be severe for two three days and chemosis may take up to three weeks to subside.

c COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

The medical literature is full of hazards and complications associated with use of Silicone Eye Sphere. It is implied & understood that since user is highly trained super-specialist. He has experience of Silicone Eye Sphere implantation. He is fully aware of all the hazards associated with use of Silicone Eye Sphere and he has studied the medical literature well before use.

The main complications of use of an eye sphere are infection and expulsion. To prevent infection, use of implant should be avoided with active inflammation. Suitable antibiotic cover should be given during and after implantation.

Perforated Silicone Eye Sphere

i INTRODUCTION

In Patient, in whom the enucleation has been done, there is no mobile base to fix prosthesis. The purpose of perforated silicone eye sphere is to maintain contour of eyeball, maintain the eye movements, provide a base for prosthesis, and maintain shape of eye socket and to prevent bony deformity. Lastly, but not the least, to give full self-confidence to the patient. It gives excellent cosmetic results. The artificial eye prosthesis, to be worn later on, will look natural due to good eye contour and almost full eye movements.

d DESCRIPTION & PRESENTATION

The perforated eye sphere is made of medical grade silicone elastomer. It is molded in one piece. The perforated eye sphere is available in four sizes. Supplied sterilized by Ethylene Oxide and in double peel open packs

Size	Code No.	Size	Code No.
14 mm	EP14	16 mm	EP16
18 mm	EP18	20 mm	EP20

i INDICATIONS

Perforated eye sphere is indicated in all cases where enucleation is done and good cosmetic results are desirable.

c CONTRAINDICATIONS

Like all implants, it is contraindicated in cases where active infection or inflammation is present. Preferably it should be inserted after six months to one year of subsidence of inflammation.

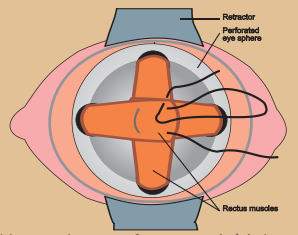
p PRECAUTIONS

Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

o OPERATIVE PROCEDURE

The implantation of silicone eye sphere may be accomplished through variety of procedures. The choice depends upon the training of surgeon, customs in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient. Following procedure is to act as guideline only.

Enucleation of eyeball is done on standard lines. Before division of rectus muscles retention sutures are applied as follows.



A double armed suture of 1.5 metric (5/0) chromic catgut is passed through the muscle 3 mm behind its insertion and transversely to the long axis of the fibers as a stitch through one

edge, a mattress in the center of the muscle and a stitch at the other edge. This suture is held in pressure forceps and lifted so that the muscle is raised from the sclera to allow passage of one blade of the strabismus scissors beneath the muscle. The muscle is then divided 1 mm behind its insertion. Same procedure is performed with all muscles. After removal of the eye ball and complete hemostasis a proper size of perforated eye sphere is selected. It should be smaller than the original eyeball. The pack is removed from Tenon's capsule and cavity sprayed with an antibiotic.

One of the retention sutures is passed through the hole in the eye sphere. The suture is inserted from the round end and so that it emerges through the depressed flat end of eye sphere. The idea is to keep the round side of eye sphere posteriorly and flat side anteriorly. The retention sutures of other three recti muscles are passed in similar fashion through the holes in perforated eye sphere. The sequence of rectus muscles is maintained i.e. 3 o clock muscle suture is passed through 3 o clock hole. In a similar fashion 6 o clock muscle suture is passed through 6 o clock hole. In this fashion all four retention sutures are passed through holes.

Now the sphere is pushed into Tenon's capsule and ends of all four muscles are drawn out through the holes. The inferior rectus is first laid into the central depression of the sphere, where it is overlapped for about 5 mm by superior rectus. The suture in the inferior rectus passes through the deep surface of the superior rectus about 4 mm behind its free end and is tied by surgical knot on the surface of the superior rectus muscle. The suture in the superior rectus muscle transfixes the edges of the inferior rectus in the form of a stitch and is then carried transversely across the united muscles to be tied by a surgical knot.A similar procedure is adopted with the other two muscles. To make it more secure, adjacent muscles are also stitched together. The free end of the superior oblique is stretched to the medial edge of superior rectus and the free end of the inferior oblique muscle is sutured to the lower margin of the lateral rectus at the equator of sphere. The closure is performed on standard lines. Adequate pressure bandage is applied.

p POST OPERATIVE MANAGEMENT

The patient may be mobilized early. On the first postoperative day the conjunctival sac is irrigated. The firm pressure dressing is maintained for 2 days, when the socket is dressed. This may be re applied with daily dressings until the fifth day. An acrylic shell may be placed in the conjunctival sac and a convex black eye shade, lined with sheet of lint, the smooth side opposed to the socket, is applied. The acrylic shell, approximately the shape and size of prostheses to be fitted later, helps to reduce the edema of the conjunctiva and to maintain the appropriate size and shape of the socket. A prosthesis is fitted in the third or fourth week of operation.

Pain may be severe for two three days and chemosis may take up to three weeks to subside.

c COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

The medical literature is full of hazards and complications associated with use of silicone eye spheres. It is implied & understood that since user is highly trained super-specialist. He has experience of silicone eye spheres implantation. He is fully aware of all the hazards associated with use of silicone eye spheres and he has studied the medical literature well before use.

The main complications of use of an eye sphere are infection and expulsion. To prevent infection, use of implant should be avoided with active inflammation. Suitable antibiotic cover should be given during and after implantation.

PRODUCT INFORMATION DISCLAIMER

G. Surgiwear Limited has exercised reasonable care in the choice of materials and manufacture of this product. G. Surgiwear Limited excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. G. Surgiwear Limited shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. G. Surgiwear Limited neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

G-Eye Hydroxyapatite Eye Sphere

i INTRODUCTION

Every human being deserves good look. After evisceration the sclera and muscles contract and shrink. The contour of eye is lost. The artificial eye prosthesis, worn later on, will always look artificial due to lack of eye movements. If evisceration / enucleation has been done in childhood the eye socket may not develop to full size and a bony deformity may occur.

The purpose of G-Eye is to maintain contour of eyeball, maintain the eye movements, provide a base for prosthesis, and maintain shape of eye socket and to prevent bony deformity. Lastly, but not the least, to give full self-confidence to the patient.

It gives excellent cosmetic results. The artificial eye prosthesis, to be worn later on, will look natural due to good eye contour and almost full eye movements.

d DESCRIPTION OF G-EYE

G-Eye is made of natural Calcium Hydroxyapatite . It is supplied in peel open packs, ready to use, sterilized by Gamma-rays. Each packet contains one G-Eye.. G-Eye is for single use only It is available in four sizes:

SIZE	CODE NO.
14 mm	MHAE14
16 mm	MHAE16
18 mm	MHAE18
20 mm	MHAE20

i INDICATIONS

G-Eye is indicated in all cases where evisceration or enucleation is to be done and good cosmetic results are desirable.

c CONTRAINDICATIONS

Like all implants, it is contraindicated in cases where active infection or inflammation is present. Preferably it should be inserted after six months to one year of subsidence of inflammation.

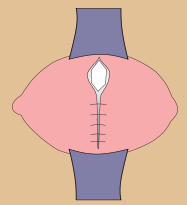
p PRECAUTIONS

Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

o OPERATIVE PROCEDURE

The implantation of G-Eye may be accomplished through variety of procedures. The choice depends upon the training of surgeon, customs in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient. Following procedure is to act as guideline only.

Insertion of G-Eye is done after completion of evisceration of eye and before closure of sclera and conjunctiva. Evisceration is done on standard lines. A proper size of G-Eye is selected.



The G-Eye is inserted into the scleral cup. The edges of sclera are sutured in a vertical line with interrupted vertical inverting mattress sutures. To avoid "dog ear" projections of sclera at each end of the sutured line, a triangle of sclera is excised from each end with the bases towards the center.

An alternative procedure is to make from the limbus four radial scleral incisions about 5 mm long at 1.30, 4.30, 7.30 and 10.30 o'clock when G-Eye is in place, two chromic catgut mattress sutures approximate the medial and lateral scleral flaps and two chromic catgut sutures join the upper and lower flaps.

In case of enucleation, cadaveric preserved sclera is used. G-Eye is put into the pouch of sclera. The pouch is properly stitched from all sides. It is placed inside the eye socket. Four recti are stitched on four side with scleral pouch.

Tenon's capsule is sewn over this with horizontal line of interrupted 1 metric (6/0) chromic catgut sutures and the conjunctiva with continuous key pattern suture of 0.5 metric (8/0) chromic catgut.

p POST OPERATIVE MANAGEMENT

The patient may be mobilized early. On the first postoperative day the conjunctival sac is irrigated. The firm pressure dressing is maintained for 2 days, when the socket is dressed. This may be re applied with daily dressings until the fifth day. An acrylic shell may be placed in the conjunctival sac and a convex black eye shade, lined with sheet of lint, the smooth side opposed to the socket, is applied. The acrylic shell, approximately the shape and size of prostheses to be fitted later, helps to reduce the edema of the conjunctiva and to maintain the appropriate size and shape of the socket. A prosthesis is fitted in the third or fourth week of operation. Pain may be severe for two three days and chemosis may take up to three weeks to subside.

c COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

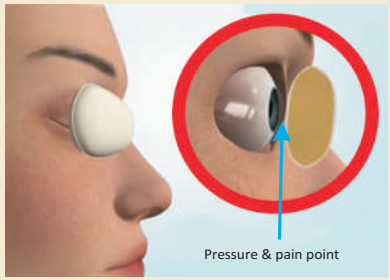
The medical literature is full of hazards and complications associated with use of Hydroxyapatite Eye Sphere. It is implied & understood that since user is highly trained super-specialist. He has experience of Hydroxyapatite Eye Sphere implantation. He is fully aware of all the hazards associated with use of Hydroxyapatite Eye Sphere and he has studied the medical literature well before use.

The main complications of use of a G-Eye are infection and expulsion. To prevent infection, use of implant should be avoided with active inflammation. Suitable antibiotic cover should be given during and after implantation.

PRODUCT INFORMATION DISCLAIMER

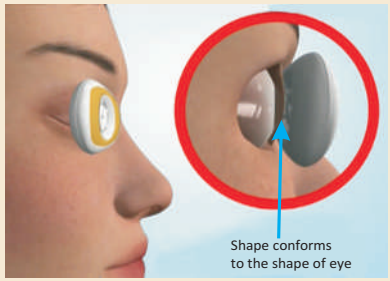
G. Surgiwear Limited has exercised reasonable care in the choice of materials and manufacture of this product. G. Surgiwear Limited excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. G. Surgiwear Limited shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. G. Surgiwear Limited neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

Eye Dress & Eye Pad



Conventional dressings bulge in the center & the eye is also round and bulge in the center so main pressure point is on cornea. Pressure on cornea causes pain & discomfort.

First time in the world, Surgiwear has invented an eye pad, which has a dimple in the center & is curved. This conforms very well to the shape of eye. It is very comfortable & puts even pressure on whole eye rather than just cornea.



It is world's best eye dressing. The beauty of this eye dress is that the pad is sealed from all sides. The pad will not shed fibers. The pad is covered by filament yarn knitted fabric from all sides. So there is no loose fiber towards patient side of the pad. A very high tech process has been used to manufacture it.

For patient it means that no fiber will go inside the eyes to irritate. It also means comfort for the patient.

The eye patch to hold the pad in place is made of soft stretchable fabric. The adhesive is soft and easy to remove. The release liner of the patch is easy to remove. All this results to more comfort for patient and ease for the surgeon.

Material of pad: Knitted filament yarn fabric and PU foam inside.

Material for patch: Non woven spun lace 100% Polyester 48 GSM

PRESENTATION

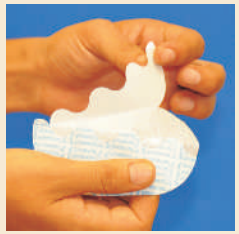
Each eye dress and eye pad are supplied sterilized by EO in peel open packs individually packed.

Item	Code
Eye Dress (eyepad+patch)	ED8
Eye Pad only	EP01

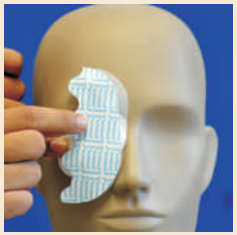
Instruction for use

1. First apply the eye pad on eye

2. Bend the adhesive patch to open the liner fingers.

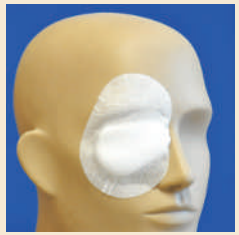


3. Remove one side of the liner



4. Apply adhesive patch on eye pad keeping the eye pad in place.

5. Remove release liner from other side as well.



6. Eye dress after application

Eye Drape

EYE DRAPE D700

Material: 22-30 gsm
SMS polypropylene fabric water repellant
Sheet Size : 100 x 70 cm
Incise Area :7 x 9 cm
Eye lid holders : (6 no)
Drainage Pouch of
Transparent PE film: (1 no)
Poly sheet lining 60 x 60 cm
Sterilized by EO

EYE DRAPE ECO E711

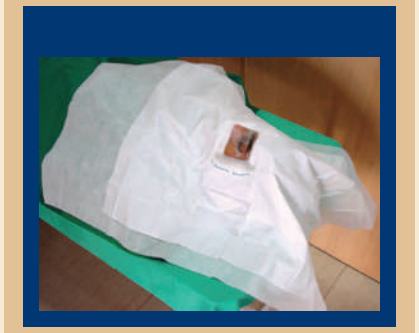
Material: 25 gsm
SMS Polypropylene fabric water repellant
Sheet Size : 100 x 70 cm,
ncise Area : 7 x 9 cm
Eye Lid Holders : (6 no)
Drainage Pouch of
Transparent PE film : (1 no)
Sterilized by EO

EYE DRAPE LARGE D702

Material: - 65 - 77 gsm
Spun Lace fabric water repellant
Sheet Size: - 120 x 160 cm,
Incise Area : 17 x 7 cm
Drainage Pouch of
Transparent PE film (1 no)
Eye Lid Holders (6 no) Sterilized by EO

EYE DRAPE BLUE D703

Material: 40-50 gsm
SMS polypropylene fabric water repellant
Sheet Size : 100 x 75 cm,
Incise Area : 7 x 9 cm
Hole in Drape : 3 x 5 cm,
Eye lid holders : (6 no)



Drainage Pouch of
Transparent PE film : (1 no)
Poly sheet lining 60 x 60 cm Sterilized by EO

EYE DRAPE NW BLUE

LARGE D704

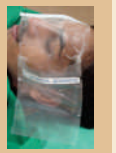
Material: 40 -50 gsm
SMS Polypropylene fabric water repellant
Sheet Size : 100 x 160 cm,
Incise Area : 7 x 9 cm
Hole in Drape : 3 x 5 cm,
Eye Lid Holders : (6 no)
Drainage Pouch of
Transparent PE film: (1 no)
Sterilized by EO

Eye Drape NW Blue Large D704

EYE DRAPE POLY BLUE

LARGE D705

Material: Blue PE film 25 micron
Sheet Size: - 100 x 120 cm
Incise Area : - 7 x 9 cm
Hole in Drape : - 3 x 5 cm
Drainage Pouch of
Transparent PE film (1 no)
Eye Lid Holders (6 no)
Sterilized by EO
Material : PE Hygiene film 25 micron
Sheet Size : 60 x 60 cm
Incise Area : 6 x 8 cm
Eye lid holders : (6 no)
Sterilized by EO



e EYE DRAPE POLY D601

Material: PE Hygiene film 25 micron

Sheet Size : 60 x 60 cm
Incise Area : 6 x 8 cm
Eye Lid Holders : (6 no)
Drainage Funnel of
Transparent PE film: (1 no)
Sterilized by EO

e EYE PATCH D602

Material: 25 micron PE film Adhesive coated with 40 - 60 gsm adhesive.
Sheet Size: 13 x 15 cm
Drainage Pouch of Transparent PE film
Eye Lid Holders (6 no)
Sterilized by EO

I-Wipe

After any ophthalmic procedure drops are put into the eye. There is flow of tears as well. Patients tend to wipe the eyes with their handkerchief, which is dirty most of the time.

Surgiwear presents I-Wipe to wipe the tears after any procedure.

* Sterile
* Chemical free
* Highly absorbent

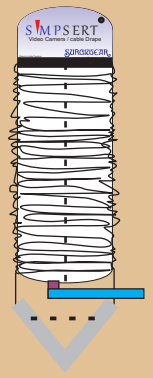
Supplied in pack of 25 nos.

Simpsert

video camera cable cover
Ultrasound cover

Length 2.5 m width 15 cm

Video camera cable cover D904
Per-operative ultrasound cover D905



Phaco I Drape

A new design of drape has been developed by SURGIWEAR for use in "Phaco Eye Surgery". It has many special features which are advantageous in phaco surgery:

- Large mouth pouch keeps table and OT dry. No dribbling of water from sides of pouch.
- Drape and inner wall of pouch is common so no flow of fluid under the pouch.
- Large pouch area distributes water weight over wide area and avoids pull on eye.
- Thick plastic sheet maintains form and shape of drape.
- Size of pouch is such that it lies on table, preventing any pull on the eye.
- In case there is some extra fluid, it can be drained through the nipple.

h PHACO I DRAPE D603

Material: 40-50 gsm PE film
Sheet Size : 60 x40 cm
Incise Area :10 x 10 cm
Eye lid holders : (6 no)
Drainage Pouch 20 x 40 cm
Sterilized by EO

h PHACO I DRAPE D604

Material: 40-50 gsm PE film
Sheet Size : 60 x40 cm
Incise Area :10 x 10 cm
Eye lid holders : (6 no)
Drainage Pouch 20 x 40 cm

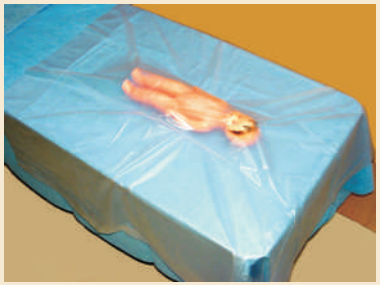
Inner layer
Material: 25 gsm
SMS Polypropylene fabric water repellant

Iodrape-2

Adhesive with Povidone Iodine

For covering incision area in all kind of surgeries
Iodine adhesive coated (45 GSM approx) PU film

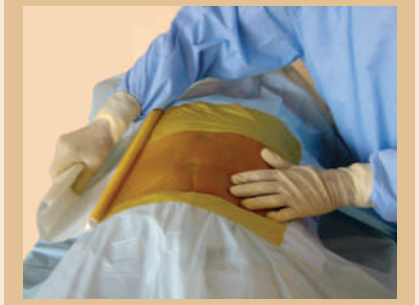
Code Number	Size	Adhesive Area
ID1010	15 X 10 CM	10 X 10 CM
ID1020	15 X 20 CM	10 X 20 CM
ID6025	90 X 25 CM	60 X 25 CM
ID3025-2	50 X 25 CM	30 X 25 CM
ID3535-2	50 X 35 CM	35 X 35 CM
ID6045-2	90 X 45 CM	60 X 45 CM
ID6060-2	90 X 60 CM	60 X 60 CM
ID6090-2	90 X 90 CM	60 X 90 CM



Head & Eye Shield

To protect operating team from infections of patient

Head & Eye Shield D804



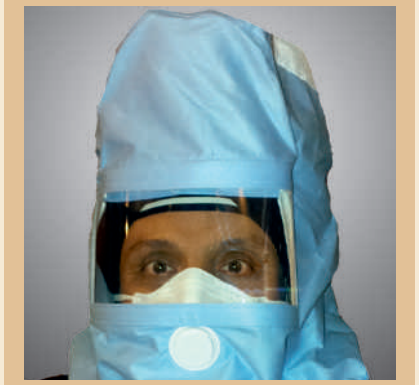
Baby Drape

For all kind of surgeries on baby also used as low cost drape

Translucent soft polyfilm

Size 1.2 x 1.2 m incise area 25 x 20 cm

Baby Drape D201



O-Scope Drape

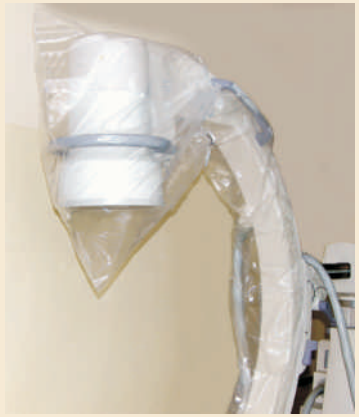
Operating Microscope drape

E214L 125 x 200cm
for three pair lens

E214M 100 x 160 cm
for two pair lens

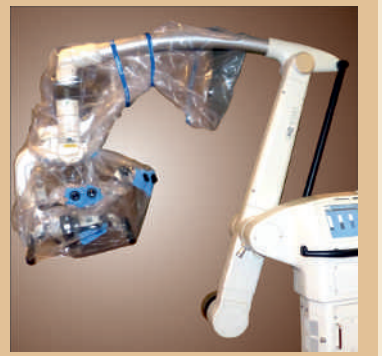
E214S 90 x 120 cm
for one pair lens
supplied sterile ready to use.

Objective lens cover sold separately.
Three sizes available diameter 60mm (OLC-01), 65mm (OLC-02) & 70 mm (OLC-03).



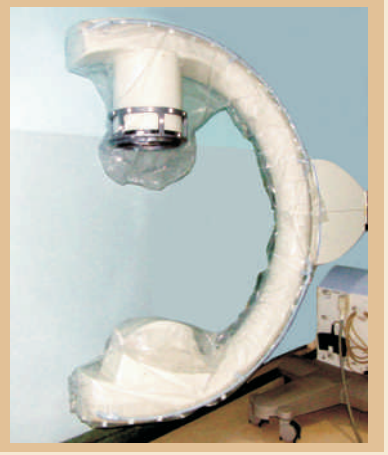
Full C-Arm cover

D307



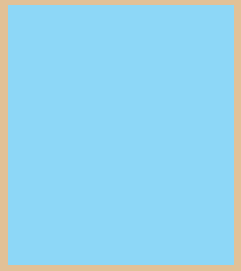
C-Arm Cover

Two part D306
Three part D306-3



Plain drapes

For Covering patient body & instrument trolleys during surgery

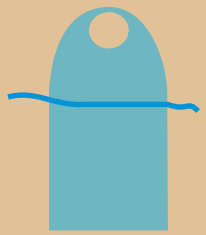


Product Name	Product Code	Size
Material: 25 micron thick PE hygiene film		
Plain Sheet Small	D300	150X120 cm
Plain Sheet	D301	210X120 cm
Plain Towel	D303	66X120 cm
Mayo's Trolly Cover S	D304	120X66 cm
Mayo's Trolly Cover L	D305	110X100 cm
Material: Spun bond NW 40gsm laminated with PE 20gsm		
Plain Sheet small NW	E310	150X120 cm
Plain Sheet NW	E311	210X150 cm
Plain Towel NW	E313	120X75 cm
Material: SMS Polypropylene Water repellant 50 gsm		
Mayo's Trolly Cover Small NW	E314	130X75 cm
Mayo's Trolly Cover Large NW	E315	150X123 cm
Material: Spun lace Non woven		
Neo natal sheet	D504	75 X 80 cm
Material: Spun lace Non woven laminated with PE 60 gsm		
Plain Sheet Int	I321	210X120 cm
Plain Sheet Small Int	I323	120X75 cm
Plain Towel Int	I327	60X75 cm

Gowns

For Covering patient body & instrument trolleys during surgery

Product	Code	Material	Protection level
Half gown	D800	Polyethylene 25micron	----
Half gown	D810	White non Woven 25 gsm	----
Full gown	D802S D802M D802L	Spun lace NW 65-77 gsm	Level 2
Full gown Eco	E812S E812M E812L	NW SMS 50gsm	Level 1
Full gown Eco 35	35E812S 35E812M 35E812L	SMS NW 35 gsm	----
Full gown Eco 25	25E812S 25E812M 25E812L	SMS NW 25 gsm	----
Full gown Viral barrier	D806S D806M D806L	Ahlstorm's BVB fabric	Level 4



- BVB means "Breathable Viral Barrier"
- All non woven fabrics are water repellent
- All full gowns are wrap around gowns and come with 2 nos Hand towels
- Spun lace NW and BVB non woven gowns have bonded sleeves For extra protection, First time in the world.
- All full gown have patented "FLUBA" fluid barrier cuffs for Extra protection