

# “MIGS”

*Minimally Invasive Glaucoma Surgery*

Working Definition / Panel Ground Rules  
Joint FDA – AGS Meeting

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# Relevant Disclosures

## *Consultant / Investigator / Advisor*

Alcon Surgical

AMO

AqueSys

Endo-Optiks

Glaukos

Ivantis

# Minimally Invasive Glaucoma Surgery

- Evolving space
- No well accepted definition
- Includes a diverse group of “alternative” glaucoma surgeries that are intended to be safer, and induce considerably less tissue disruption than traditional procedures

# Surgical Safety and Efficacy

- In general surgical safety and efficacy are related to...
  - Mechanism of IOP reduction
  - Reservoir for aqueous egress
  - Complexity of surgical maneuvers
  - Extent of tissue manipulation
  - Frequency of complications and /or adverse events

# MIGS: Reservoir for Aqueous Outflow

## **MIGS are diverse**

- *Best categorized by the recipient reservoir which has significant influence on both safety and efficacy*
  - Schlemm's canal
  - Suprachoroidal Space
  - Sub-conjunctival Space

# Schlemm's Canal

- Most physiological
- Synergistic with innate outflow pathway
- Mechanism maximizes safety
  - ESVP provides “safety net” barrier, eliminating risk of hypotony
  - Accordingly, efficacy has similar limitations
  - Success dependent on viability of distal outflow system

# Suprachoroidal Space

- Less synergistic to innate mechanism
- Hypotony theoretically possible
- No theoretical limitation to efficacy based on resistance of the recipient bed
- Disuse atrophy of physiological system is possible post-operatively
- Greater theoretical risk than canal based procedures
  - Large trials may prove or disprove this premise for a particular device

# Subconjunctival Space

- Not synergistic to innate mechanism
- No theoretical barrier to efficacy
- Hypotony theoretically possible
- Disuse atrophy of physiological system possible
- *Extra-scleral* egress introduces risk of endophthalmitis
- Greater theoretical risk than canal based procedures
  - Large trials may prove or disprove this premise for a particular device



# Minimally Invasive Glaucoma Surgery

Ultimately...

***MIGS classification may need to be “earned”...***

**Based on:**

- *at least modest efficacy*

**and more importantly...**

- *an enhanced safety profile as determined by well controlled clinical trials*

## Minimally Invasive Glaucoma Surgery - Implantable Devices

*Definition for today's panel discussions...*

- Intended to lower IOP via an outflow mechanism
- Either ab-interno or ab-externo approach
- Very limited or no scleral dissection
  - *needle or device penetration/perforation of sclera allowed*
  - *procedures involving significant scleral dissection excluded*
- Minimal or no conjunctival manipulation
  - *limited peritomy or small incision allowed*

# Minimally Invasive Glaucoma Surgery - Implantable Devices

## Definition for today's panel discussions...

### EXISTING EXAMPLES OF MIGS FOR THIS AFTERNOON'S FDA-AGS PANELS:

#### Canal Based

##### ***Trabecular microbypass stents***

- ✓ *Glaukos iStent*
- ✓ *Ivantis Hydrus*

#### Suprachoroidal Based

##### ***Ab-interno suprachoroidal stents***

- ✓ *Glaukos iStent Supra*
- ✓ *Transcend CyPass*

#### Sub-conjunctival Based

##### ***Ab-interno, trans-scleral filtration devices***

- ✓ *AqueSys Xen*

##### ***Ab-externo trans-scleral filtration devices***

- ✓ *InnFocus Microshunt*

# Minimally Invasive Glaucoma Surgery - Implantable Devices

## Definition for today's panel discussions...

**EXCLUDED FOR TODAY'S FDA-AGS PANEL DISCUSSIONS**  
**(But may be included in other MIGS definitions)**

### Canal Based

#### ***Ab-Interno Trabeculectomy***

- ✓ *Trabectome – no device implanted*

#### ***Ab-Interno Trabeculotomy***

- ✓ *iScience catheter – no device implanted*

### Suprachoroidal Based

#### ***Ab-externo suprachoroidal stents***

- ✓ *Solx Gold Shunt – more extensive scleral dissection*

### Sub-conjunctival Based

#### ***Ab-externo trans-scleral filtration devices***

- ✓ *Alcon ExPress – more extensive scleral dissection*

# Panel Considerations

## Safety and Efficacy Standards for MIGS

- Safety and efficacy are inexorably linked
- While all procedures should have at least modest efficacy...
  - safer procedures might be held to more modest efficacy standards...
  - while procedures with greater risk may be expected to have greater efficacy
- The indications for each MIGS may differ based on *both* efficacy and safety considerations

## Minimally Invasive Glaucoma Surgery - Implantable Devices

*Despite the diverse nature of the procedures collectively known as MIGS...*

- Panels challenged (as much as possible) to establish uniformity of clinical trials involving MIGS implantable devices:
  - ✓ *Eligible Patients and Severity Endpoints*
  - ✓ *Safety Endpoints*
  - ✓ *Efficacy Endpoints*

***Thank-you***