NEOVISTA EPI-RAD 90 INTRAOCULAR DEVICE

2010

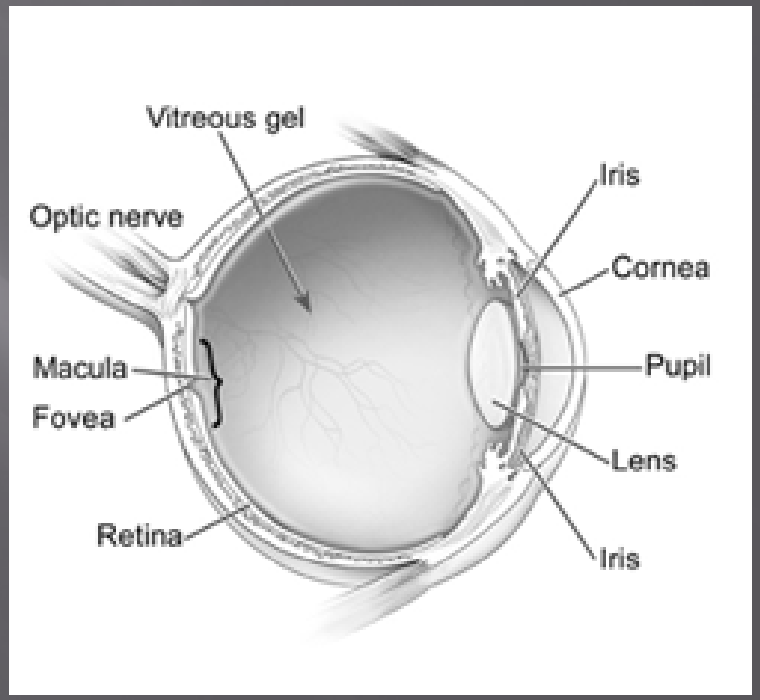
Age-Related Macular Degeneration

- "AMD"
- Affects the macula, the part of the eye that allows you to see fine detail
- Is a disease associated with aging that gradually destroys sharp, central vision
- AMD is a leading cause of vision loss in Americans 60 years of age and older.
- Two types: wet and dry.

Normal vs. AMD vision fields

Related Anatomy

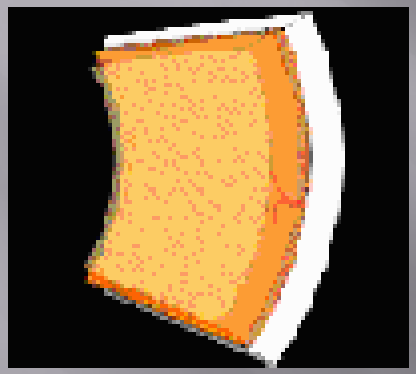
- The macula is located in the center of the **retina**, the light-sensitive tissue at the back of the eye.
- The retina functions to convert light, or an image, into electrical impulses. The retina then sends these impulses, or nerve signals, to the brain.

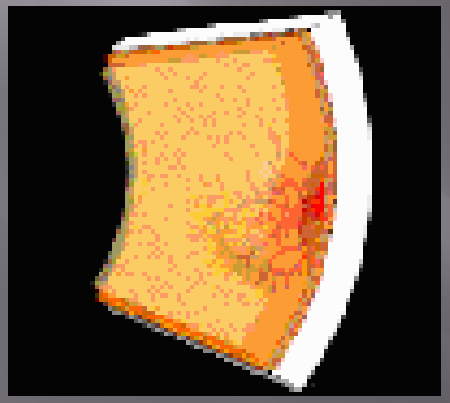


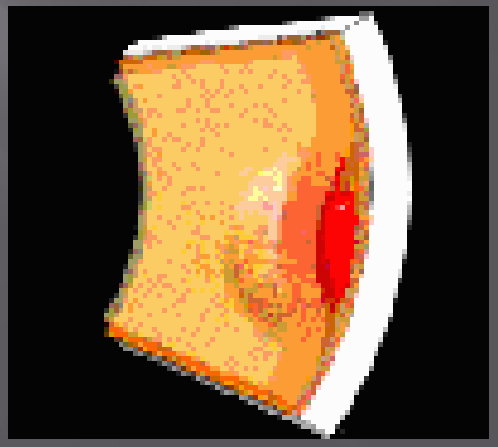
Wet or Exudative AMD

- Makes up 10-15% of cases of AMD
- **Choroidal Neovascularization** is the growth of abnormal blood vessel under the macula
- The vessels are not very strong and leak blood and fluid
- This fluid and blood collection cause the macula to elevate on the posterior surface of the eye or the retina to detach

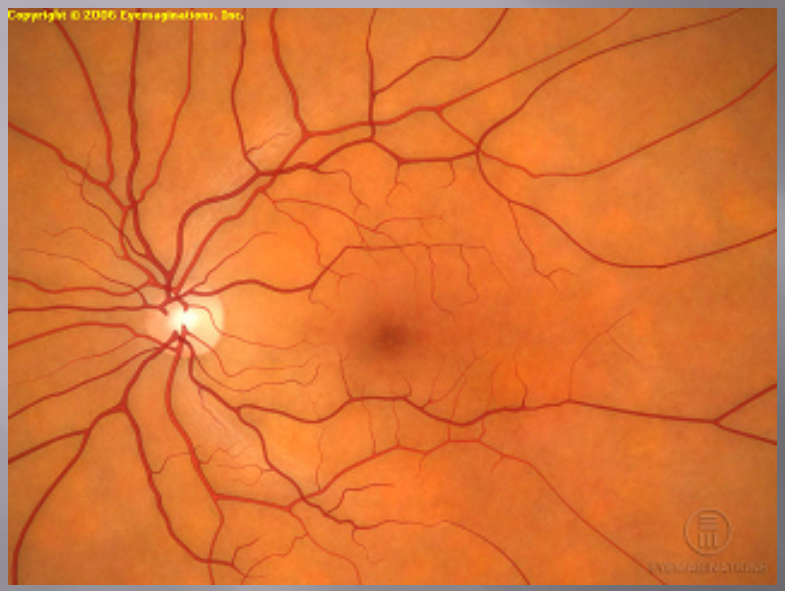
Choroidal Neovascularization

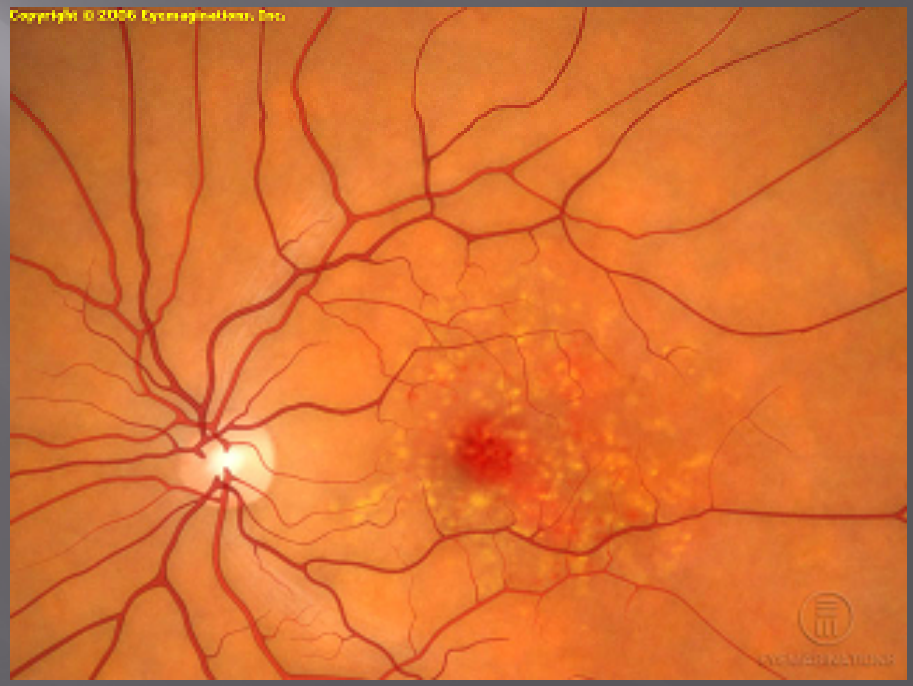






Normal vs. AMD



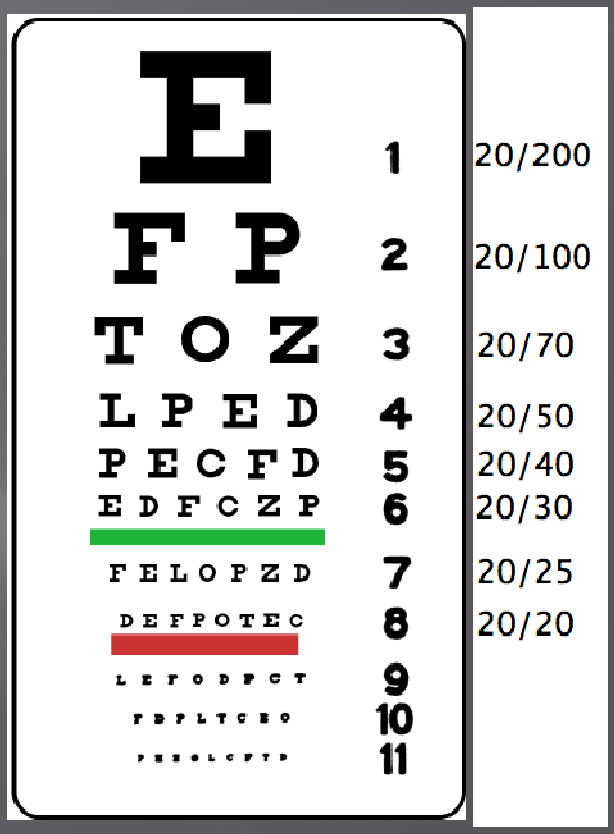


Some Symptoms

- Rapid loss of central vision
- Significant loss of visual acuity
  - Going from 20/20 to 20/80
- Hemorrhages in eye
- Changes in pigment of eye
- Distorted vision (Amsler Grid Test)
- Slow recovery of visual function after bright light exposure

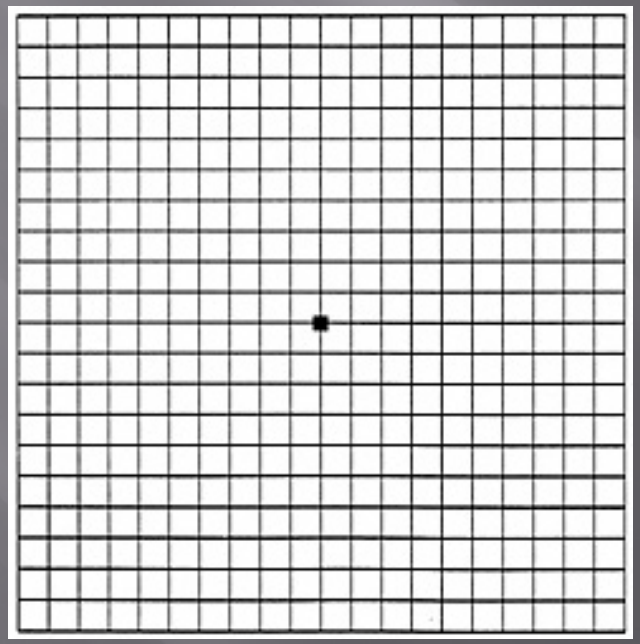
Testing for AMD

- Visual acuity test with eye chart
- Dilation of eyes to allow for examination of retina and optic nerve
- Tonometry to measure pressure inside the eye



Amsler Grid Test

- Used to monitor health of macula
- If positive, lines will appear wavy, bent, distorted or even missing.



Who is at risk?

- Age greater than 65
- Smoking
- Obesity
- Caucasian Ethnicity
- Family history
- Female gender

Treatment Options for Wet AMD

- Laser Surgery
  - The new, leaking vessels are destroyed
- Photodynamic therapy
  - Drug called Verteporfin is injected into peripheral vein
  - Drug seeks new blood vessels
  - Light is shined into eye for 90 seconds to activate medication

Treatment Options for Wet AMD

- Injections of anti-VEGF medications into eye
  - Medication inhibits growth factor which promotes growth of abnormal blood vessels
- NeoVista
  - Strontium 90 beta radiation surgical procedure

The Treatment Process

- The treatment utilizes a typical vitrectomy, with radiation delivered using the NeoVista system
- Procedure is performed under local anesthesia, and the entire procedure normally takes less than 1 hour
- Radiation delivery using the NeoVista device is highly focal, penetrating the target area to a depth of only 3 mm and covering an area slightly larger than 5 mm in diameter

Equipment Utilized

- Multichannel Tester (MCT)
- Delivery Device

Multi-Channel Tester (MCT)

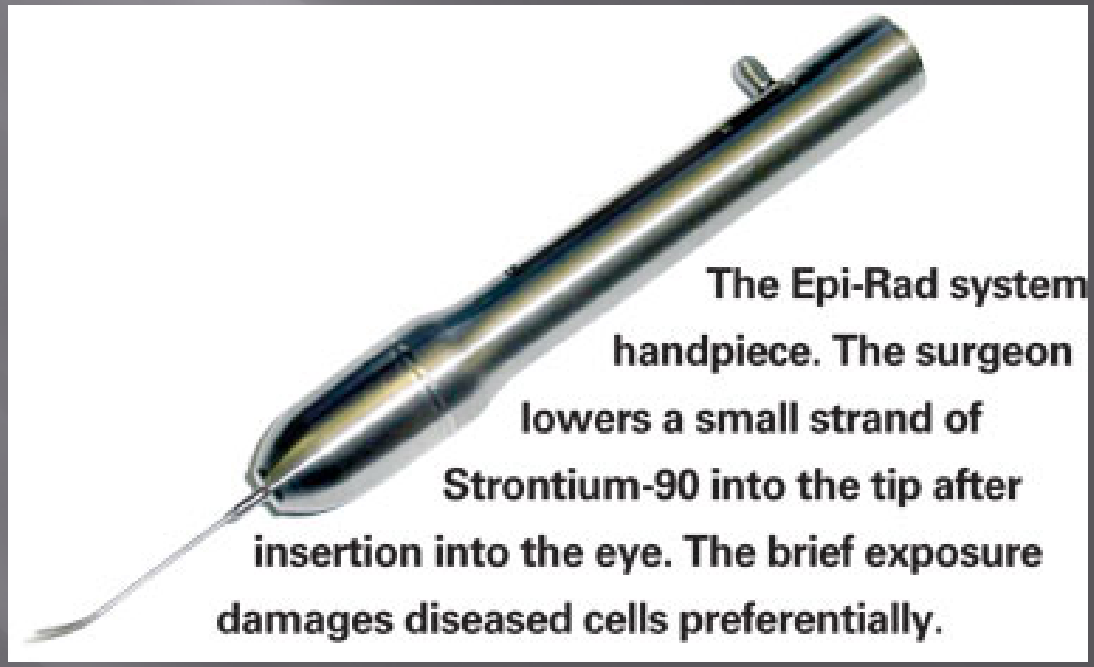
- Used to verify correct position of radioactive source within cannula tip
- Has multiple measurement sites to verify radiation at different portions of source

Multi-Channel Tester

- Channel 1
  - Detects radiation from the distal part of the source
- Channel 2
  - Detects radiation from the proximal portion of source
- Readings are taken and show up as a display on the screen
- Numbers must fall within a designated range or the handpiece cannot be used

The Handpiece

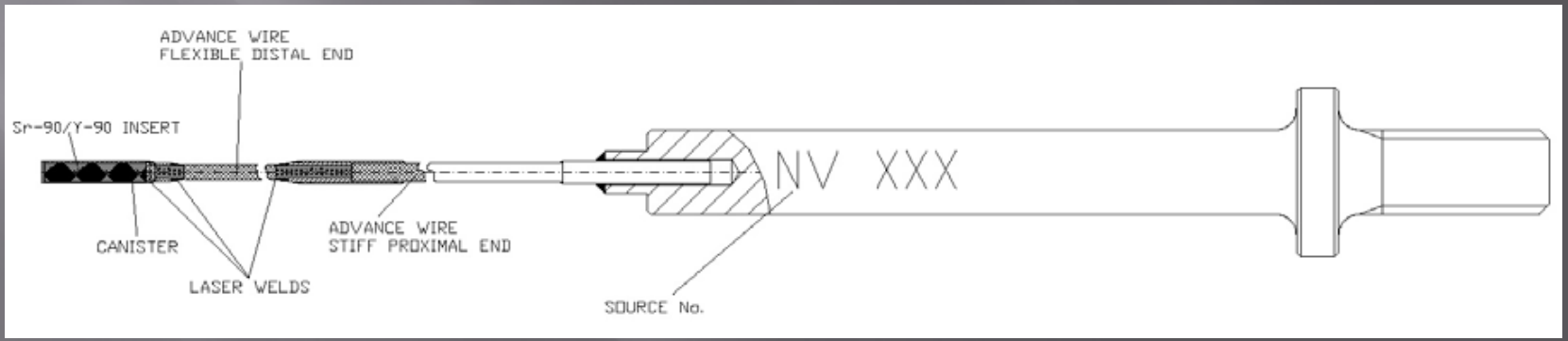
The device consists of a hand piece with a 20-gauge cannula, within which resides a retractable radiation source (the radioactive isotope strontium-90).



The Epi-Rad system handpiece. The surgeon lowers a small strand of Strontium-90 into the tip after insertion into the eye. The brief exposure damages diseased cells preferentially.

Radiation Protection

- Special design of hand piece protects both operator and patient
- Shielding
  - Inner shield constructed of Aluminum
    - Blocks beta radiation
  - Outer shield constructed of Densimet
    - Reduces secondary or bremsstrahlung



Radiation Source

- Based on Strontium-90/Yttrium-90 beta emitting isotopes
- Maximum source activity is 555 MBq
- Source has half-life of 29 years
- Source Activity:
  - 11-15 mCi
- Source Size
  - 0.52mm (diameter)
  - 2.5 mm (length)

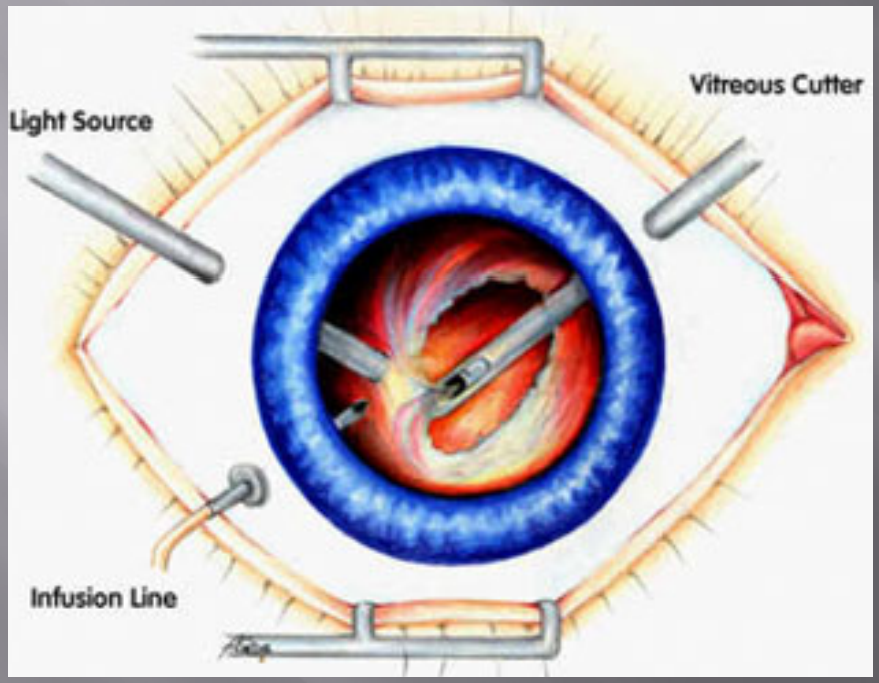
Equipment Prep Procedure

- Source is retracted into handpiece
- Device is removed from MCT
- Delivery device is placed in ready position

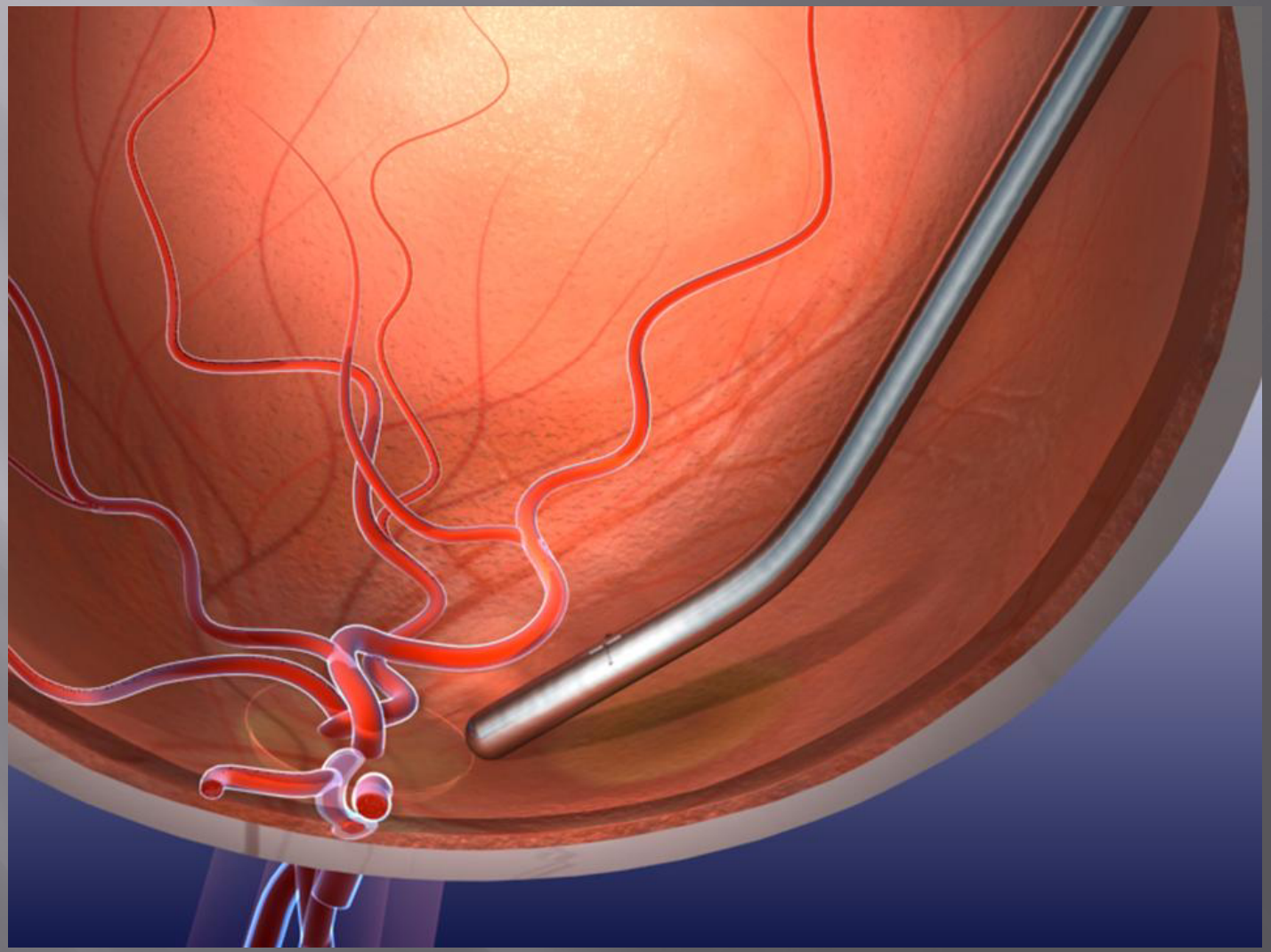
Equipment Prep Procedure

- An initial test with no delivery device in place to measure the radiation levels in the treatment area
- MCT Functionality Tests are done with Delivery Device in place
  - 1st measurement is with source retracted
  - 2nd measurement is with source engaged

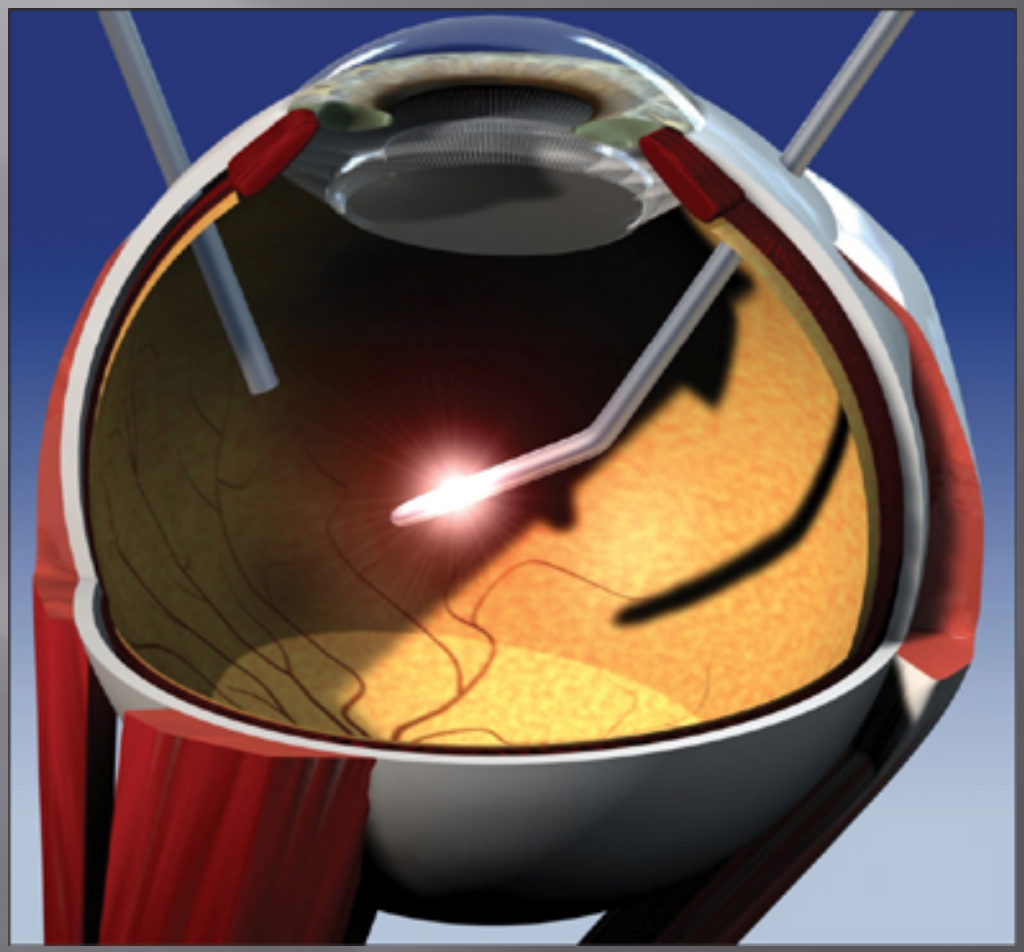
Access with Three-Port Core Vitrectomy



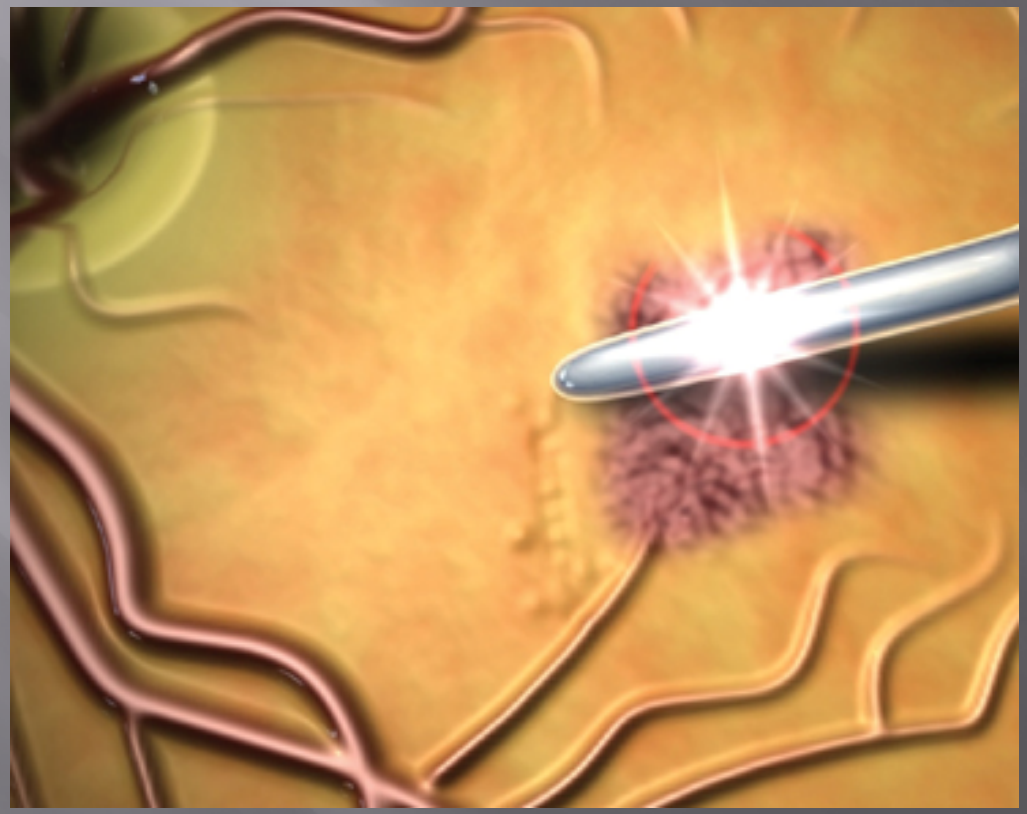
Delivery Device inserted through Port



Cannula tip is guided to lesion



Delivery Device is left in place for prescribed "dwell time" and then source is retracted



Post Procedure

- Device is removed from port
- Testing is done with handpiece in MCT to verify dosage to patient

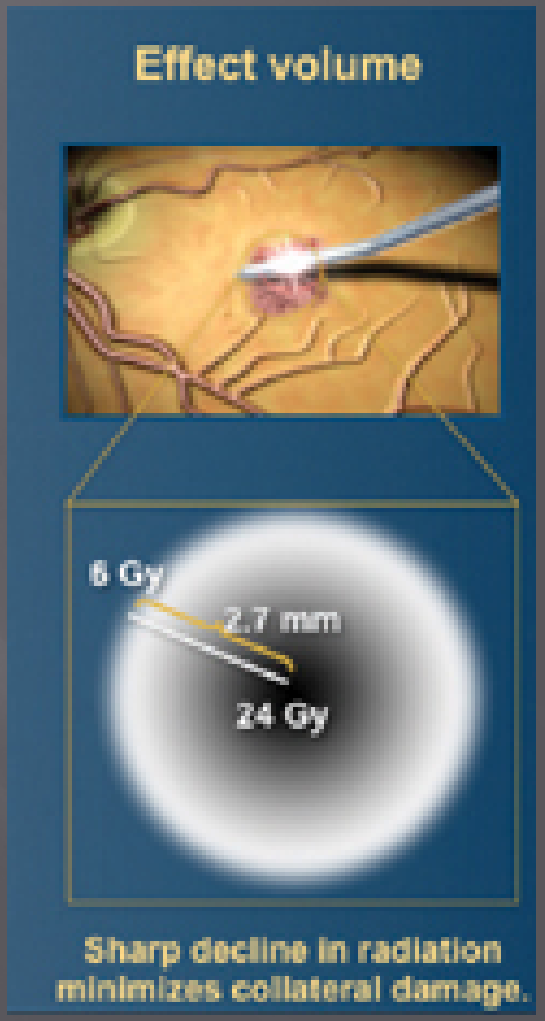
Procedural Video

Radiation Dosages to Patient

- Because beta radiation decreases exponentially with increasing distance from the source, the delivery of radiation to neighboring structures is low.
- A targeted dose of beta radiation is administered directly at the site of the AMD lesion—but the energy will only penetrate about 3 millimeters (about 1/8 inch) and spread about 5 millimeters (less than 1/4 inch).

Radiation Dosages to Patient

- The macular lesion receives 24 Gy
- The optic nerve receives 2.4 Gy
- The lens receives 0.0006 Gy
- Whole-body dose of radiation received by the patient < typical chest x-ray



References

- http://www.neovistainc.com/index.html
- http://www.revophth.com/index.asp?page=1_13285.htm