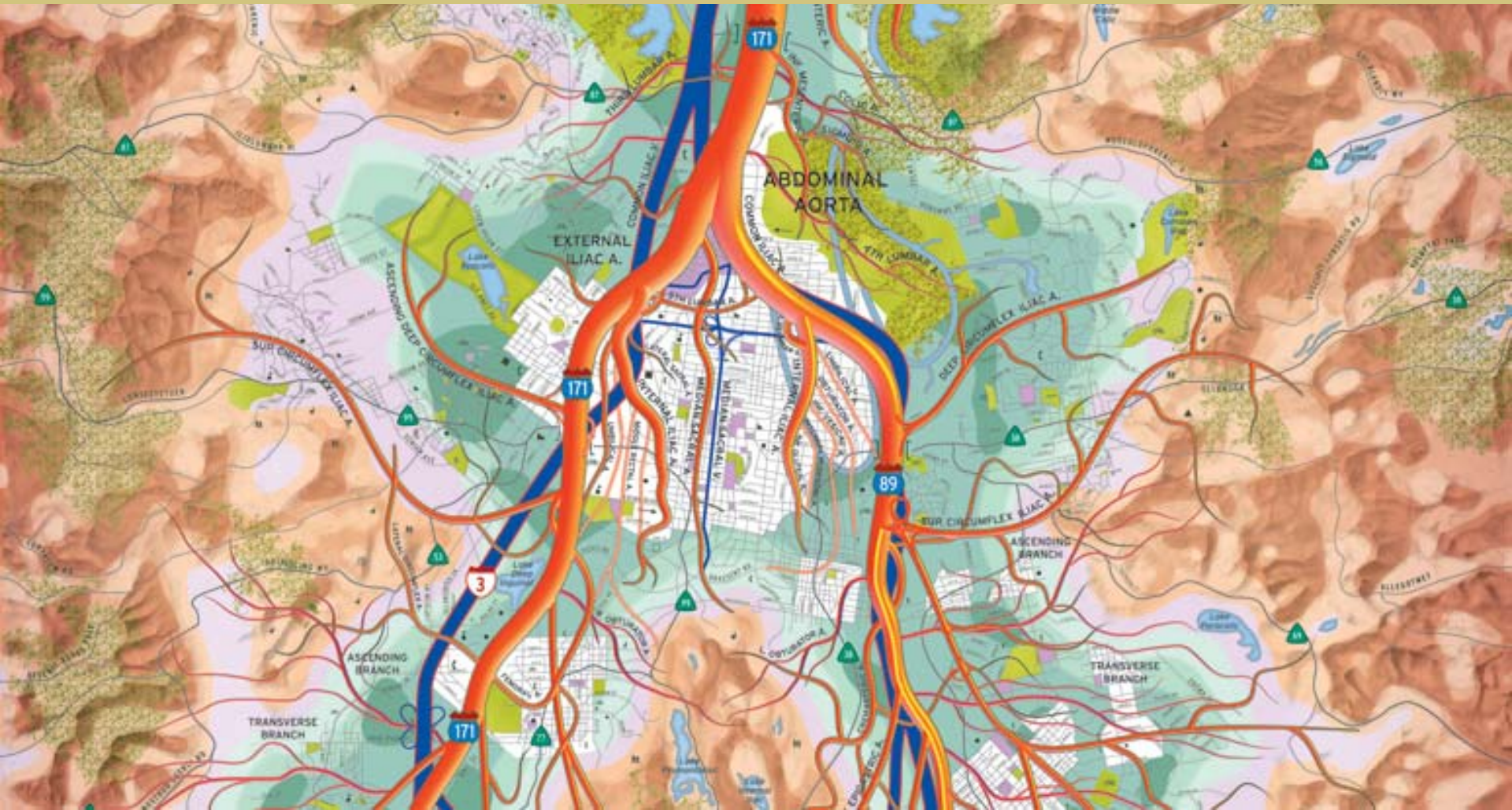
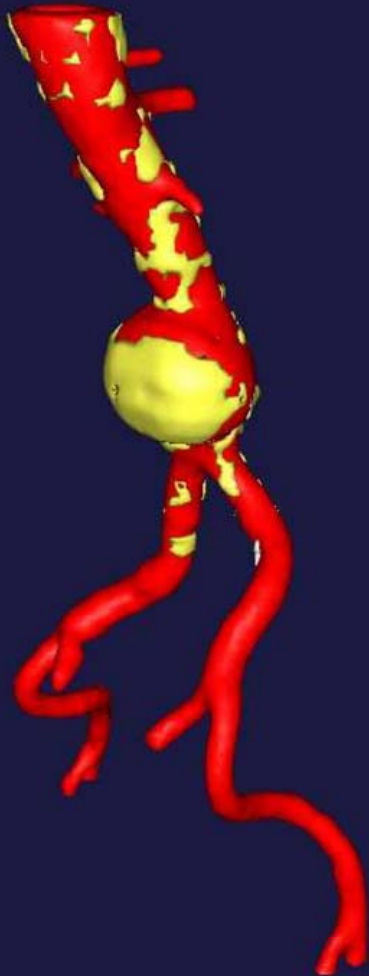


# Community Awareness Program

## Endovascular Repair of Abdominal Aortic Aneurysms

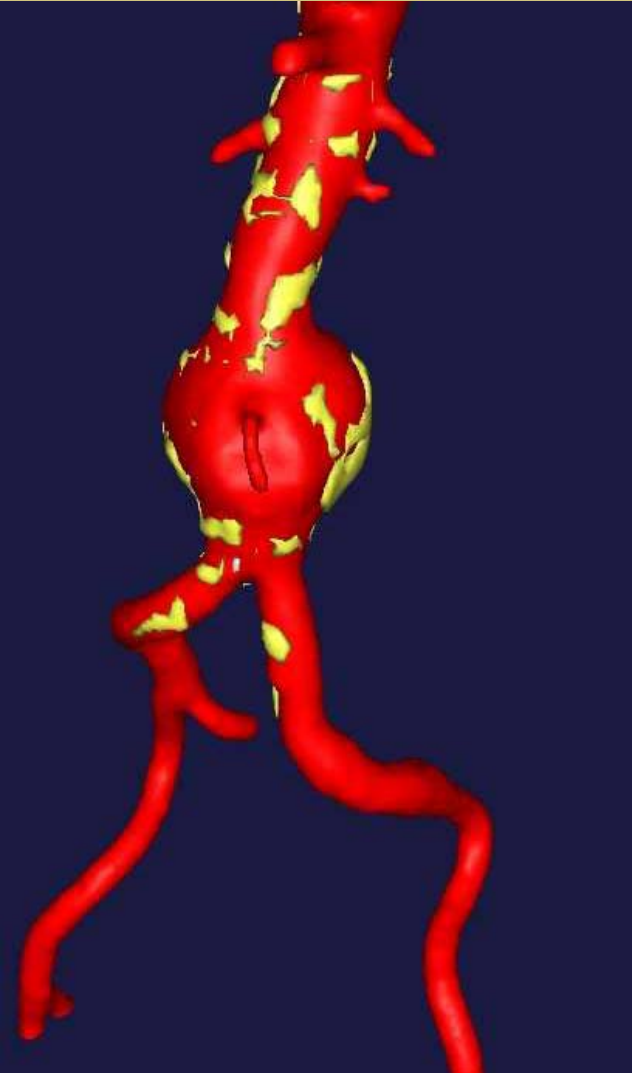


# Aneurysm Definition



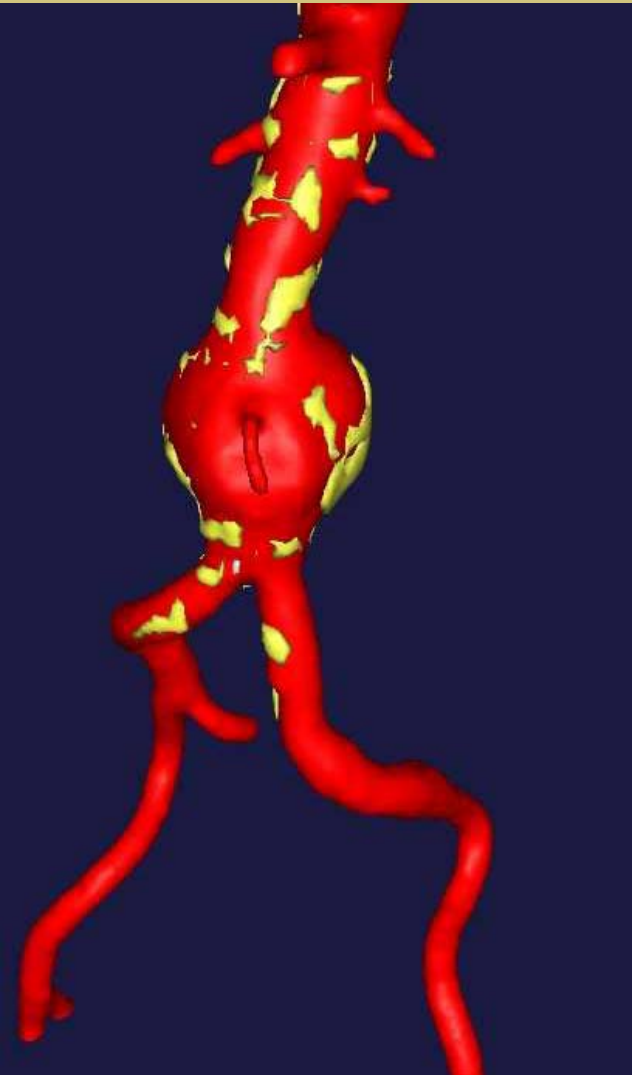
- The abnormal enlargement or bulging of an artery caused by an injury or weakness in the blood vessel wall
- A localized dilatation of the aorta with an increase in diameter of  $>1.5$  times its normal diameter

# AAA Facts



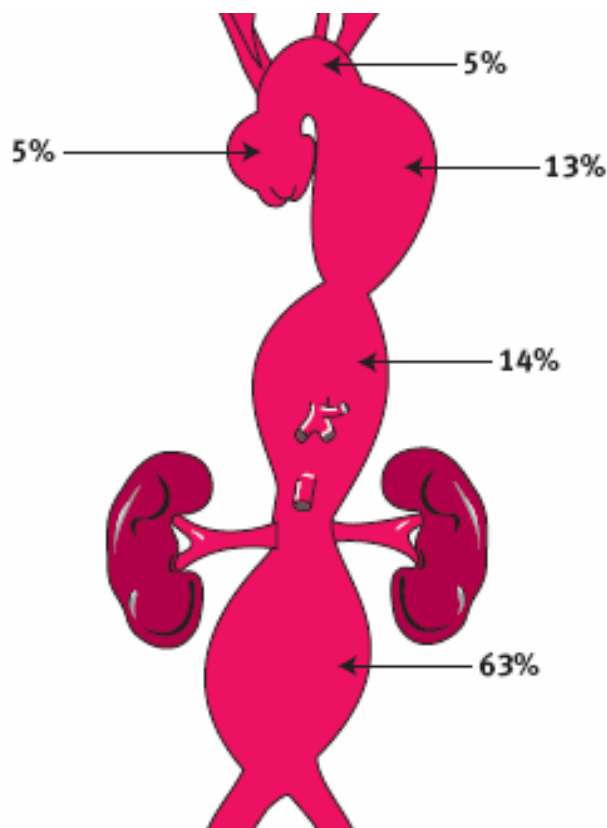
- Over the last three decades, incidence has tripled<sup>1</sup>
- 1.5 million people in the US have AAAs<sup>2</sup>
- Men present 4:1 over women<sup>3</sup>
- Risk increases for men by 40% every 5 years after age 65<sup>4</sup>
- 15,000 deaths annually due to ruptured AAAs in the US – 13<sup>th</sup> leading cause of death<sup>2</sup>

# AAA Facts



- Most AAAs are infrarenal – patients often have other aneurysms, including iliac (41%) and femoropopliteal (15%) lesions<sup>1</sup>
- Hypertension (30 – 40%)<sup>4</sup>
- Smoking (6:1)<sup>4,5</sup>
- > 50,000 procedures per year for AAA repair<sup>6</sup>

# AAA Incidence and Location

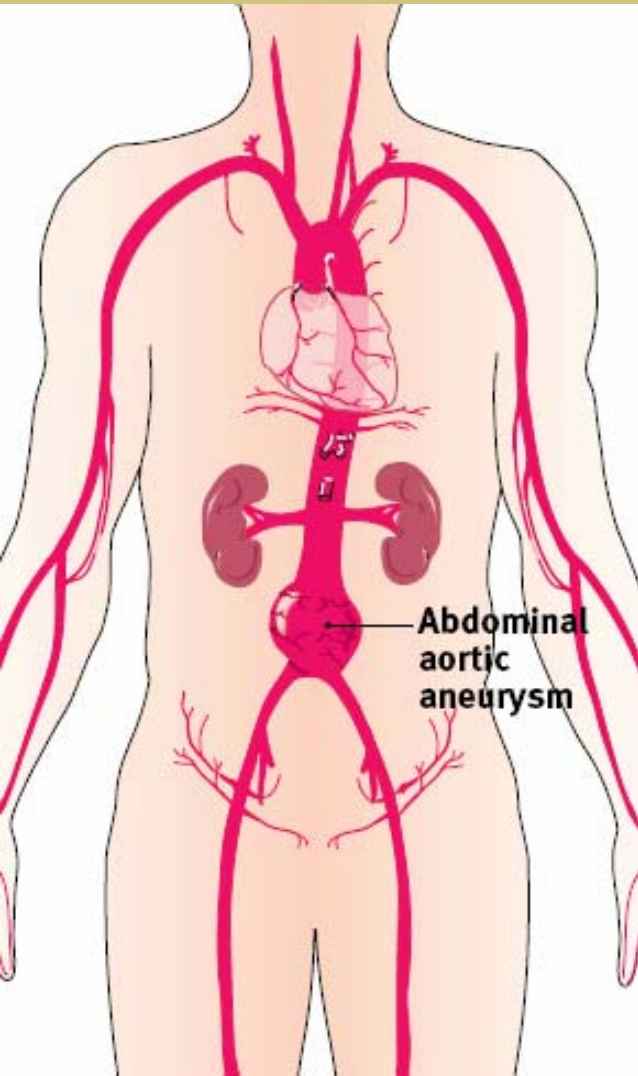


- Incidence of aortic aneurysms

Each year, physicians diagnose approximately 200,000 people in the United States with AAA.

([www.vascularweb.org/contribution\\_pages/patient information](http://www.vascularweb.org/contribution_pages/patient%20information))

# Clinical Challenge



- The majority of patients are asymptomatic
- Approximately 40% of patients with ruptured AAAs die prior to presentation to the emergency department<sup>6</sup>
- Only 10% to 25% of individuals with ruptured AAAs survive until hospital discharge



# Risk Factors

## Major Risk Factors

- Current or former smoker
  - A history of smoking has been associated with a 3- to 5- fold increase in AAA prevalence across all age groups<sup>3</sup>
- Family history of AAA
- Age – over 60
- Gender
  - Abdominal aneurysms are four times more common in men than women<sup>4</sup>
    - 5% of US males over 60 are estimated to have a AAA



# Risk Factors

## Lesser Risk Factors

- Hypertension
- Atherosclerosis
- CAD



# Prevalence of AAAs

- AAAs encountered more frequently in contemporary practice due to:
  - Better diagnosis
  - True increase in prevalence
- Prevalence as well as rupture risk increase sharply with age<sup>7</sup>
- Population over the age of 65 will grow from 34 million to 50 million by 2020<sup>8</sup>

# Symptoms



- AAA is often called a “silent killer” because there are no obvious symptoms of the disease ([www.SIRweb.org](http://www.SIRweb.org))
  - Three out of four aneurysms show no symptoms at the time they are diagnosed ([www.SIRweb.org](http://www.SIRweb.org))
- Possible symptoms may include:
  - Abdominal pain
  - Pain in the lower back that may extend to the buttocks, groin or legs
  - Pulsating sensation in the abdomen
- Symptoms indicating a rupture may include:
  - Sudden onset of severe back or abdominal pain
  - Nausea
  - Dizziness, fainting and/or sudden weakness



# Diagnostic Methods

- Physical exam, palpation and auscultation
- Abdominal Ultrasound
  - Commonly used as a primary screening tool
  - Provides details of the vessel wall and plaque
- Computed Tomography Arteriography (CTA)
  - Most accurate test to determine size and location
  - Readily available
  - Eliminates the need for invasive angiography but requires IV contrast



# Diagnostic Methods

- Arteriogram
  - Less useful modality
  - Unable to accurately delineate AAA due to thrombus lining the flow lumen
  - Provides images of associated arterial occlusive disease

# When to Treat

## DESCRIPTION OF AORTIC ANEURYSM



Fusiform  
Aneurysm



Saccular  
Aneurysm

- Elective repair of AAA is recommended when the maximal aneurysm diameter is 5.5 cm or more<sup>6</sup>
- Aneurysms that have a saccular morphology may be considered for repair even if < 5 cm in diameter
- Aneurysms that have a fusiform morphology may be considered for repair if they are painful, have caused distal embolization, or are rapidly enlarging (>0.5 cm/year)<sup>5</sup>



# AAA Treatment Options

- Medical Management / Monitor
  - Wait, watch and control hypertension
  - Typically reserved for aneurysms < 5 cm that are not rapidly expanding or causing symptoms
  - Most commonly monitored with regular CT scans or ultrasound examinations



# AAA Treatment Options

- Surgical Treatment
  - Elective repair has a perioperative mortality rate of about 3 - 5%<sup>3</sup>
  - 22 - 30% morbidity
  - High risk surgical group includes: cardiac, renal, pulmonary disease, and morbid obesity<sup>9</sup>
  - Patients > 75 years of age have a higher perioperative mortality rate<sup>9</sup>
  - Average 7 to 10 days hospitalization<sup>10</sup>
  - Emergency repair: mortality 40 - 50%<sup>11</sup>
  - Coronary events are the leading cause of death following repair of AAAs<sup>12</sup>



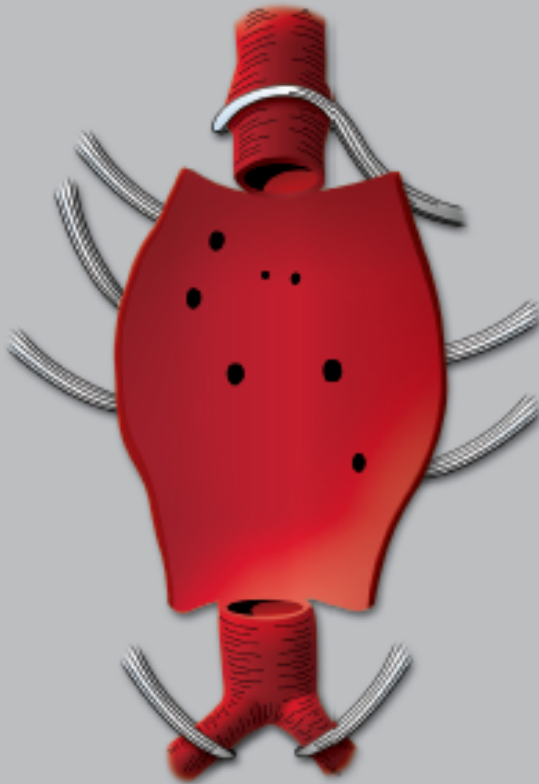
# AAA Treatment Options

<b>Risk Diameter (cm)</b>	<b>Rupture (% per year)</b>
<b>&lt; 4</b>	<b>0%</b>
<b>4 - 5</b>	<b>0.5 - 5%</b>
<b>5 - 6</b>	<b>3 - 15%</b>
<b>6 - 7</b>	<b>10 - 20%</b>
<b>7 - 8</b>	<b>20 - 40%</b>
<b>&gt; 8</b>	<b>30 - 50%</b>

- AAA Expansion Rate<sup>14</sup>
  - Although a number of studies have found that small AAAs expand at approximately 0.5 cm in diameter per year, individual patients show considerable variation in aneurysm expansion rates

# Open Surgical Repair

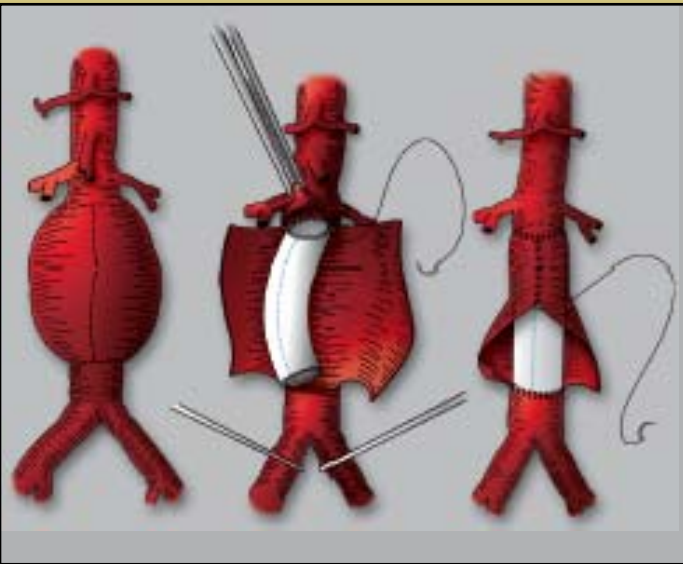
## AORTIC EXPOSURE



## Surgical Treatment - Two Methods:

- Transabdominal
  - Most common approach
- Retroperitoneal
  - Reduced gastrointestinal impairment following operation

# Open Surgical Repair



- Results of Standard Open Repair

- Effective and durable...but

- 4 - 5% mortality in population-based studies<sup>15,16,17</sup>
- Recovery 2 - 4 months<sup>18</sup>
- High risk patients often denied repair<sup>19</sup>
- 5-year survival rate of 46%<sup>9</sup>

# Open Surgical Repair



- Complications
  - Infection
  - Limb thrombosis
  - Aortoenteric fistula (AEF)
  - Paraplegia
  - Pseudoaneurysm formation at anastomoses



# Open Surgical Repair

- Infection: Catastrophic event<sup>1</sup>
  - Mortality (25 - 88%)
  - Incidence (1 - 2%)
  - Mean time to onset (6 months - 4 years)
  - 8 - 10% of all aneurysms yield positive bacterial cultures

# Endovascular Repair



- Principles of Endovascular Aortic Repair (EVAR)
  - Anchoring and secure fixation of endoluminal device above and below AAA in normal arterial segments
  - Hemostatic seals exclude AAA from circulation
  - Exclusion and depressurization prevent AAA rupture

# Endovascular Repair



- Goal of EVAR
  - Accurate placement and secure attachment of a sutureless prosthesis across an aneurysm, to effect repair quite similar to standard open surgical grafting but using only:
    - Small groin incision
    - Minimal anesthesia

# AAA Endovascular Repair

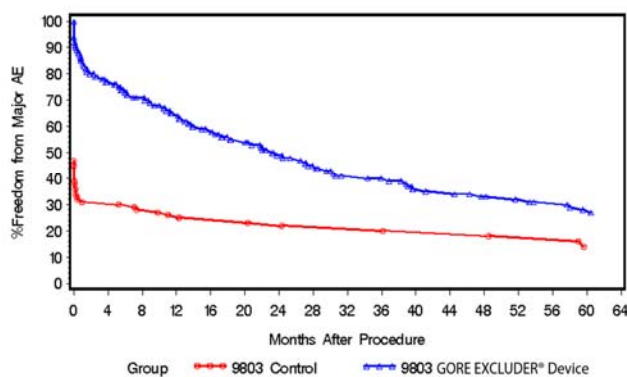


- Potential Benefits of EVAR
  - Shorter hospital stay; 1 - 3 days vs. 5 - 13 days<sup>2,16</sup>
  - Safer option for high risk patients: most have significant concomitant disease (e.g., CAD, COPD)<sup>2</sup>
  - Anesthesia:<sup>15,16</sup>
    - General = shorter time and less blood loss
    - Regional = epidural
    - Local = percutaneous (closure devices)
  - Overall lower morbidity
  - Lower mortality rate
  - Patient comfort<sup>14</sup>

# AAA Endovascular Repair

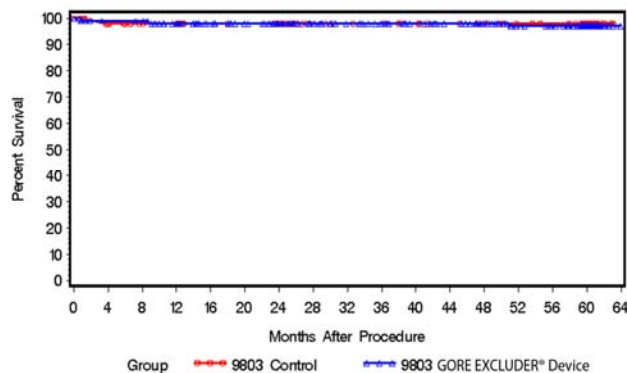
## Freedom from Major Adverse Events Through 5 Years

GORE EXCLUDER® Device vs. Control



## 5-year Aneurysm Related Survival

GORE EXCLUDER® Device vs. Control

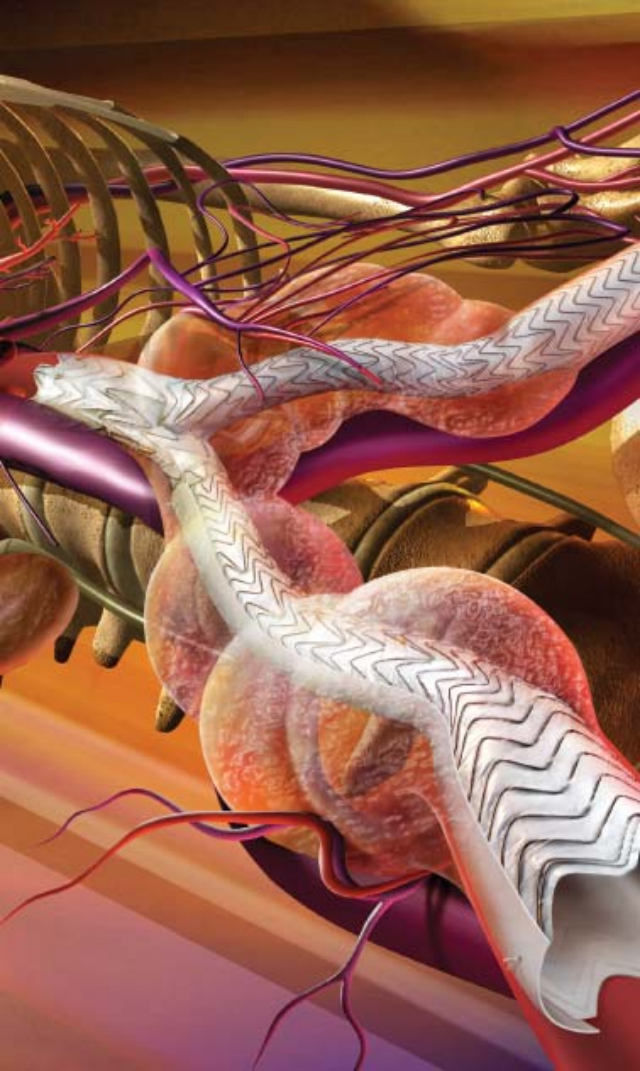


- GORE EXCLUDER® AAA Endoprosthesis
  - US Pivotal Trial results at 60 months (n = 235 patients enrolled)\* demonstrate the GORE EXCLUDER® AAA Endoprosthesis is:
    - Safe
      - Significantly lower rate of major adverse events
      - Comparable survival
    - Effective
      - 0 ruptures
      - 1 post-procedure migration
      - 1 stent fracture
      - 0 graft tears
      - 0 post-operative limb disconnections
      - 0 deployment failures
      - 10% total endoleak rate\*\* (0% Type I, 8% Type II, 0% Type III and IV, and 2% indeterminate)
      - 100% cumulative patency
      - Low post-procedure conversion rate of 4.3%

\* Site Reported Data Through October 3, 2005

\*\* At 5 years

# Summary



- The annual rupture risk of 5 - 6 cm AAA is approximately 3 - 15%, and the average growth (expansion) rate is approximately 0.5 cm per year
- Although open surgical repair is effective and durable, morbidity remains substantial and other limitations exist
- In appropriate patients, EVAR offers a safe and effective alternative with many potential advantages



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