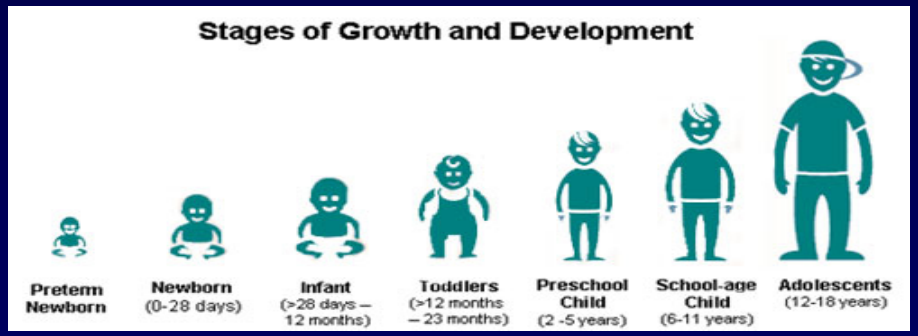
Pediatric Devices for Rare Diseases: Clinical Perspective

James D. Geiger, MD
Professor Department of Surgery
Executive Director UM Pediatric Device Consortium

University of Michigan
C.S. Mott Children's Hospital

Pediatric Challenges

- Size range
- Tissue properties
- Physiology



FDA Regulatory Definitions:

Pediatric Subgroup	**Approximate Age Range**
Newborn (neonate)	from birth to 1 month of age
Infant	greater than 1 month to 2 years of age
Child	greater than 2 to 12 years of age
Adolescent	greater than 12 to 21 years of age

Congenital Lung Lesions- CPAM

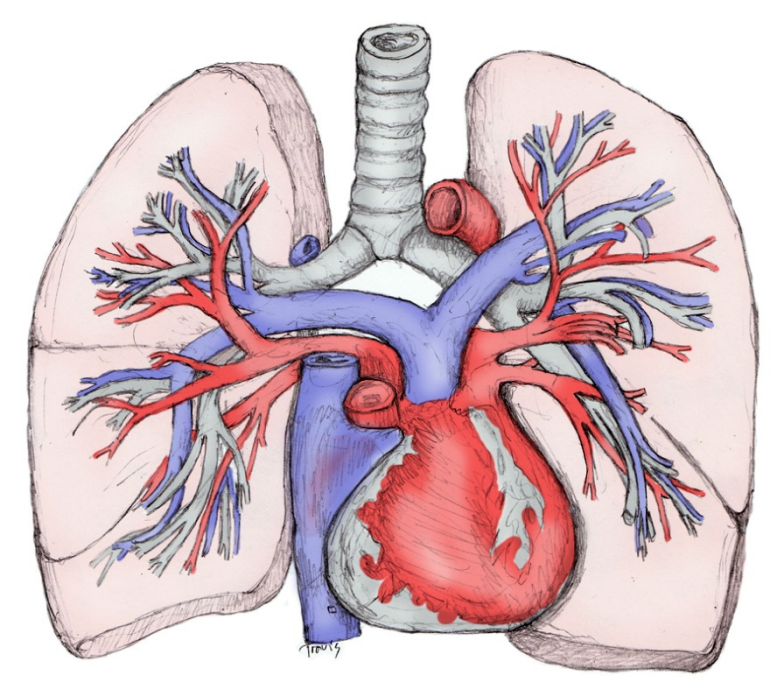
- Rare developmental anomaly of the lower respiratory tract
- Estimated incidence at 1:25,000-1:35,000 births
- Prenatal diagnosis common
- Complications
  - Infection
  - Malignancy

Treatment for Congenital Lung Lesion- CPAM

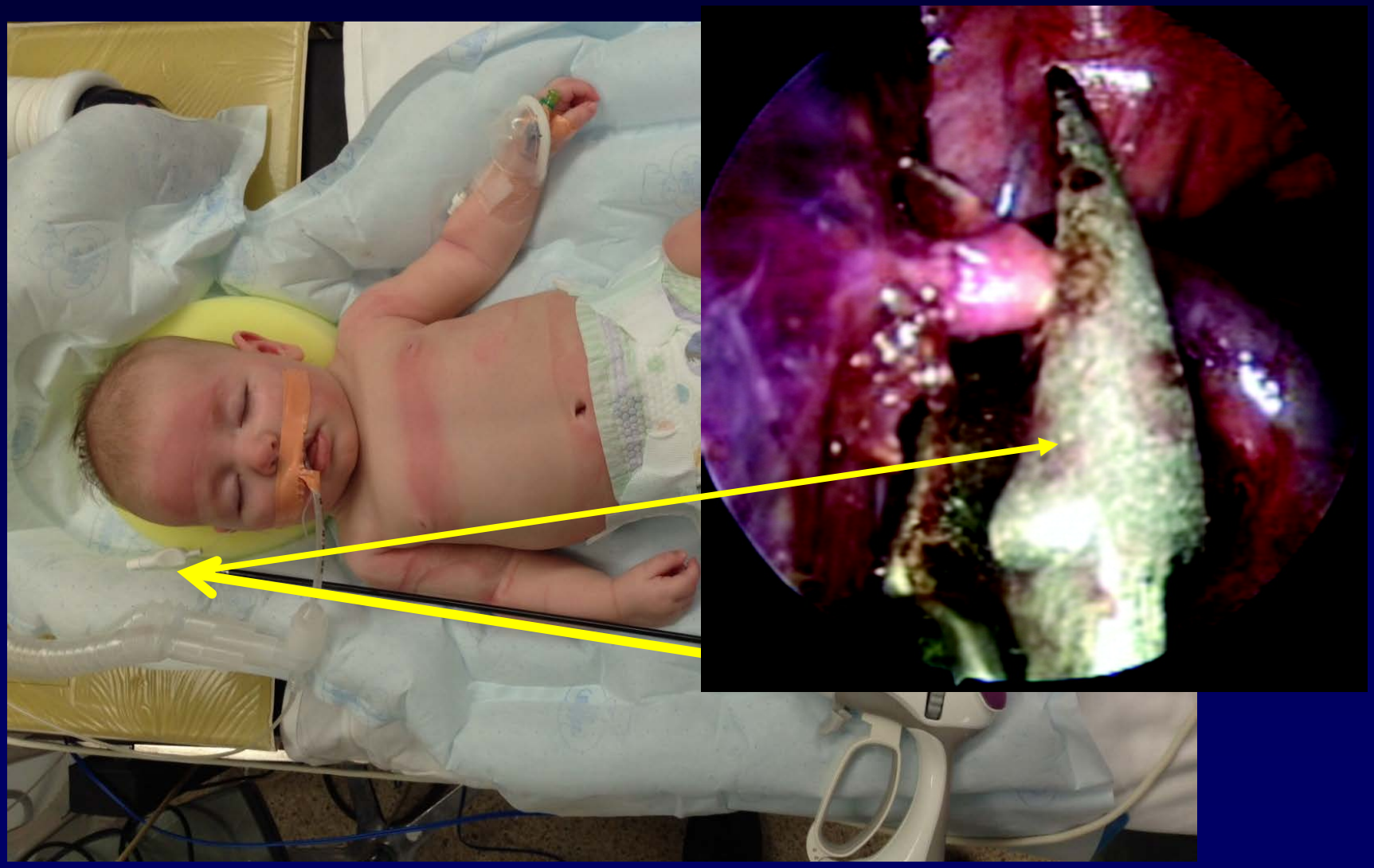
- Observation
- Surgery
  - Open-thoracotomy
  - Closed (MIS)-thoracoscopy

Surgery for Congenital Lung Lesion- CPAM

- Anesthesia considerations
- Surgery
  - dissection/exposure
  - divide blood vessels
  - divide Bronchus



Electrosurgical Devices

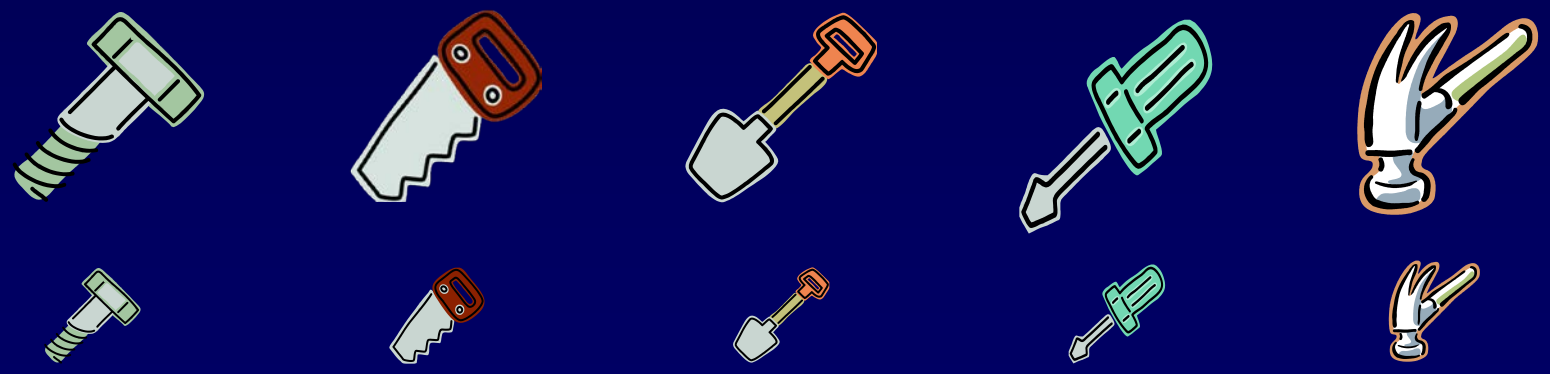


Staplers

- Require 12 mm port
- Staple cartridge 10 mm
- Smallest staples too large for neonatal vessels
- Articulation requires large working space

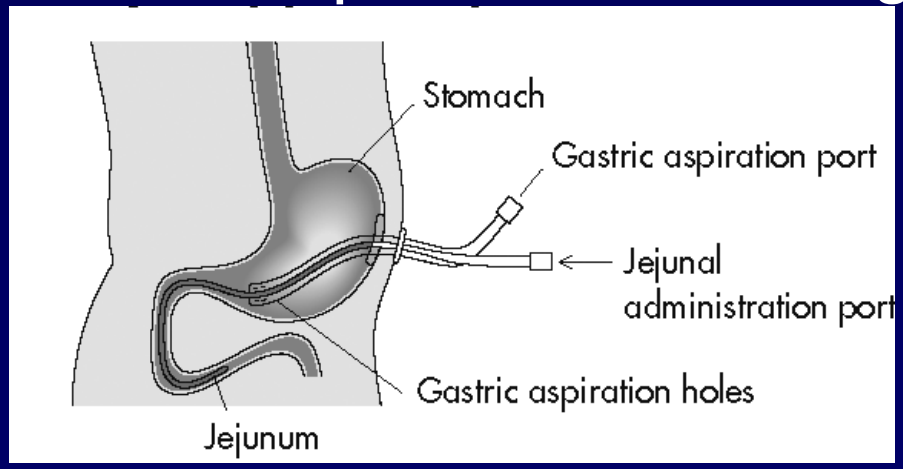
There is hope

Smaller scale tools for minimally invasive surgery are being developed and marketed, to meet the needs of the pediatric population



Percutaneous Gastro-jejunal tube placement

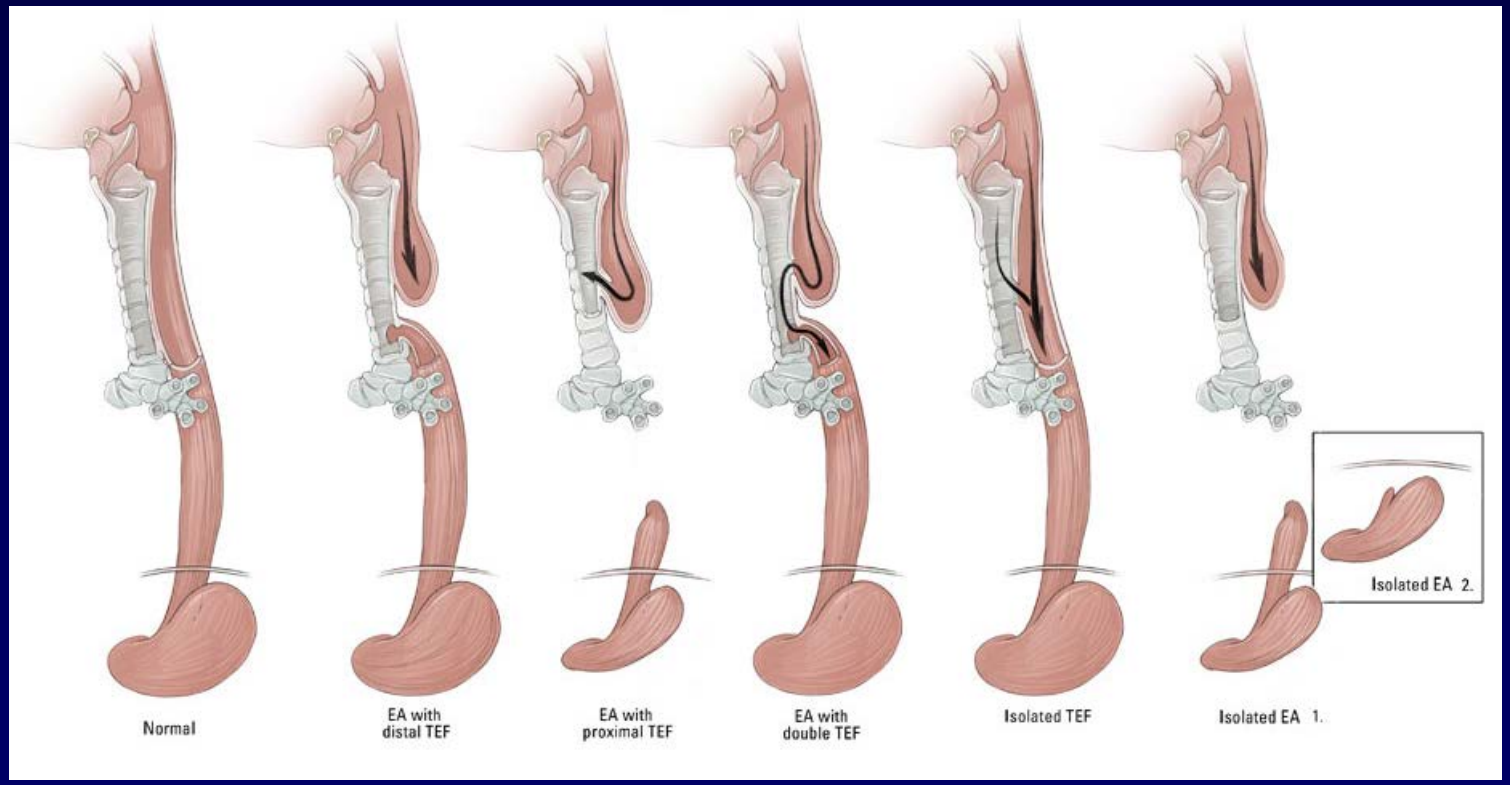
- Feeding tube which allows feeds beyond stomach
- Pediatric tubes available
- Needs still not always met
  - Extremes of size (neonates)
  - Endoscopes, wires too big, long, etc.



Gastro-jejunal tube placement

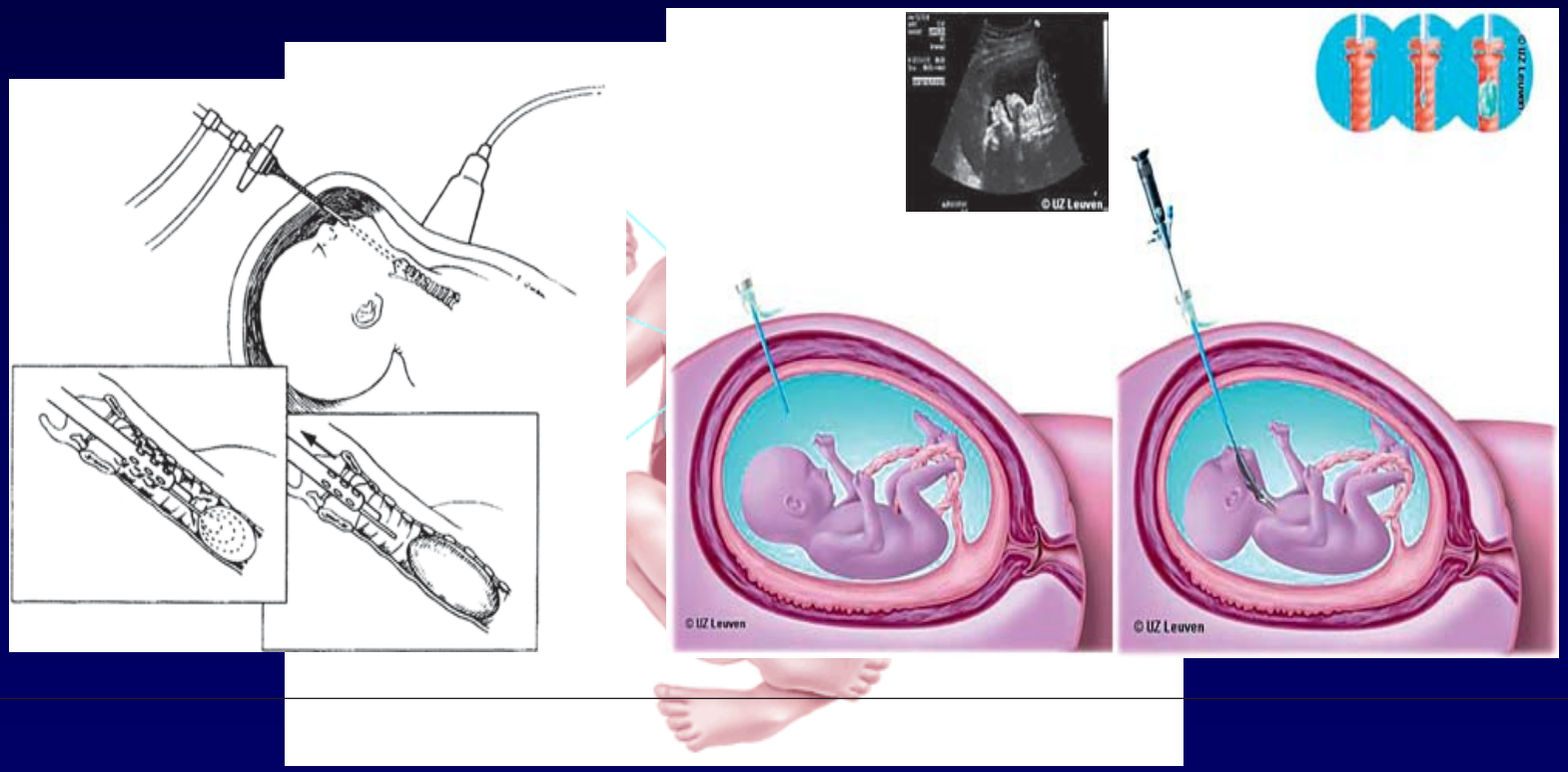
No shortage of needs: Great opportunity

- Esophageal atresia



No shortage of needs: Great opportunity

- Congenital diaphragmatic hernia



How can we achieve medical innovation for children?

- Need better data
- Sustained programs in pediatric device development
- Funding
- Accelerated lower cost regulatory process
- Increased government incentives-especially for major med-device manf.
- Unique collaborations-academic, industry, government

How can we achieve medical innovation for children?

- Novel business development concepts- LC3
- Pediatric Device Clinical Trials Network
- Reimbursement – value conscious innovations
- Global markets
- Celebrate success