

SUMMARY OF SAFETY & EFFICACY

BURKE CONGENITAL THORACOSCOPY INSTRUMENTS NOV 19 1996

SPECIFIC INDICATION OF USE:
PATENT DUCTUS ARTERIOSUS INTERRUPTION

- DEVICE DESCRIPTION:** These instruments are equivalent to Thoracoscopy instruments for adult sizes but have a reduced dimension with a modified geometric configuration to meet reduced size requirements. These are modifications therefore of equivalent surgical instruments that can be used in general pediatric surgery but also have been designed specifically for pediatric thoracoscopic surgery. Instruments that are needed for the surgical procedures are cannula, lung retractor, clip appliers, grasping forceps with ratchets, scissors, hooks, and clamps. These instruments have specific overtures and dimensions suited for this surgical procedure.
- INTENDED USES:** Burke Congenital Thoracoscopy Instruments are intended for use for General Pediatric Surgery where visualization in confined anatomic spaces minimizing tissue trauma are needed. These instruments are designed to be used in Video-Assisted Thoracoscopic Surgery (VATS). Where size constraints are limiting and immature tissues are potentially vulnerable to mechanical injury.
- INDICATIONS:** Pediatric Thoracoscopic Procedures
Patent Ductus Arteriosus Interruption (PDA)
- CONTRA INDICATIONS:** For PDA patients with a ductal diameter over 1 cm calcification, presence of a transcatheter device within the ductal lumen, patients with dense pleural adhesions.
- STERILIZATION:** These stainless steel instruments are reusable. They are provided non-sterile and may be autoclaved or ethylene oxide gas sterilized.