

DEC - 4 1996

CONFIDENTIAL



K963328
P174

SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address: American Medical Systems
10700 Bren Road West
Minnetonka, Minnesota 55343

Phone and Fax Numbers: 612-930-4666 (phone)
612-930-6496

Contact Person: Kris Teich

Date of Summary Preparation: August 21, 1996

Establishment Registration Number: 2183959

II. DEVICE NAME

Device Common or Usual Name: Penile Inflatable Implant

Device Trade or Proprietary Name: AMS Ambicor™ Penile Prosthesis

Classification Name Penile Inflatable Implant (21 CFR §876.3350)

III. PREDICATE DEVICE

Penile Inflatable Implant (21 CFR §876.3350)

IV. DEVICE DESCRIPTION

The Ambicor Penile Prosthesis is a device intended for implantation in the body to correct erectile impotence. The device consists of two cylinders and a single pump. The cylinders are implanted in the corpora cavernosa of the penis and a pump which is implanted in the scrotum. Each time the pump bulb is squeezed, saline is pumped from the reservoir into the cylinders. This step produces the inflation that makes the penis rigid. The Ambicor Penile Prosthesis is deflated by bending the penis (and specifically, the cylinders) to a 55 - 65° angle and maintaining that position for 6-12 seconds before releasing

The device comes with 12 rear tip extenders (RTE). Each RTE provides 0.5 cm of additional length to the device. A total of 12 RTEs are packaged with each device, potentially providing an additional 3.0 cm of length expansion per cylinder (6 RTEs/cylinder). The device consists primarily of silicone elastomers and incorporates polyester fabric, an expanded polytetrafluoroethylene (PTFE) sleeve, a polyacetal, and stainless steel components.

V. INDICATIONS FOR USE

The AMS Ambicor Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence) in men who, after appropriate patient history, diagnostic evaluation and discussions with the urologist of other alternative treatment methods, are determined to be suitable candidates for implantation surgery.

VI. COMPARISON TO PREDICATE DEVICE

For the following reasons, we maintain that the Texapol material is substantially equivalent to the Delrin material and that the change in materials poses not new questions of safety or effectiveness.

MATERIAL/DEVICE COMPARISON		
FEATURE	AMBICOR Penile Prosthesis (with Delrin components)	AMBICOR Penile Prosthesis (with Texapol components)
510(k)	K930163	To be assigned
Intended Use	Erectile Dysfunction	Erectile Dysfunction
Material	Silicone Elastomer Polyester Fabric Expanded PTFE Stainless Steel Nylon Delrin	Silicone Elastomer Polyester Fabric Expanded PTFE Stainless Steel Nylon Texapol
Sterilization	Steam/EtO SAL of 10 ⁶ EtO Residuals within acceptable limits	Identical
Packaging	Foil pouch placed inside a Tyvek/Mylar pouch	Identical
Anatomical Placement	Cylinders in the corporal bodies, pump bulb in the scrotum	Identical

MATERIAL/DEVICE COMPARISON		
FEATURE	AMBICOR Penile Prosthesis (with Delrin components)	AMBICOR Penile Prosthesis (with Texapol components)
Functional Characteristics	Inflation occurs by squeezing the pump bulb thereby pushing fluid from the reservoir to the cylinders. Deflation occurs by bending the cylinders (penis) at a 55-65° angle and holding this angle for 6-12 seconds before releasing the cylinders. Fluid transfer occurs between the outer tube and woven tubing into the reservoir via the pump bulb	Identical
Identity and dimensional specifications of components	Delrin is the current material for the poppet, stiffener, and snap washer used in the manufacture of Ambicor	The dimensional specifications were not changed based on the material change from Delrin to Texapol. All new material parts will be qualified prior to use.

A. Bench Testing

The physical, mechanical, and biocompatibility tests used to evaluate Texapol provide data which supports our determination that Texapol is substantially equivalent to Delrin and is suitable for use in the Ambicor Penile Prosthesis.

B. Principles of Operation

Inflation occurs by squeezing the pump bulb thereby pushing fluid from the reservoir and pump to the cylinders. Deflation occurs by bending the cylinders (penis) at a 55-65° angle and holding this angle for 6-12 seconds before releasing the cylinders. Fluid transfer occurs between the outer tube and woven tubing into the reservoir and pump via the pump bulb

C. Device Performance

The Ambicor Penile Prosthesis manufactured with Texapol components is comparable with respect to intended use and

technological characteristics to the Ambicor Penile Prosthesis manufactured with Delrin components.

D. Material Comparison

Acetal resins are highly crystalline plastics based on formaldehyde polymerization technology. These resins are strong, rigid, and have good moisture, heat and solvent resistance. Both homopolymer and copolymer acetal resins can be produced.

Delrin 100 and Delrin 500 are classified as homopolymers. Homopolymers generally have higher melting points, increased hardness, higher resistance to fatigue, increased rigidity, higher tensile and flexural strength and less elongation than copolymers.

Texapol 5203 and Texapol 5209 are classified as copolymers. Copolymers have excellent balance of properties and processing characteristics including high tensile and flexural strength, fatigue resistance and hardness. They retain much of their toughness through a broad temperature range. Copolymers process easier and faster than the conventional homopolymer grades.

By comparison, both homopolymers and copolymers are suitable for use as component materials in the Ambicor Penile Prosthesis.

In summary, American Medical Systems has provided information within the 510(k) premarket notification to indicate that the Ambicor Penile Prosthesis manufactured using components made from Texapol is safe and effective for its intended use in the treatment of penile erectile dysfunction. Texapol has been shown to be comparable to Delrin in regards to the technological characteristics and intended use of the device. The data and information provided within this 510(k) premarket notification adequately supports our claim of substantial equivalence.