Urological

pAguamedicina Structural Hydrogel Medical Device Material

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A wholly owned subsidiary of Boston Scott Corporation

polyaguamedicina used as a **medical device** (Catheter) raw material should provide an immediate reduction in heath care costs; increased patient comfort and quality of care.

polyaguamedicina is a hydrolyzed polyacrylonitrile; used in a unique proprietary manufacturing process produces **structural 100% hydrogel** devices, comprised mostly of water (or aqueous media) essentially **built out of water**.

polyaguamedicina is currently **FDA approved** (for pediatric ureteral stents), exhibiting true inherent **bio-compatibility** and mechanical **compliance** is expected to reduce the incidence of **encrustation**; **infection** & tissue **irritation**.

polyaguamedicina provides antifouling rather than antimicrobial performance; that is no additives are required whereby biofilms are not expected to adhere and migrate

Comparison of Medical Device (Catheter) Materials

This is not a hydrogel **coating**, the **hydrogel material is the catheter; there is no** "coating" to erode.

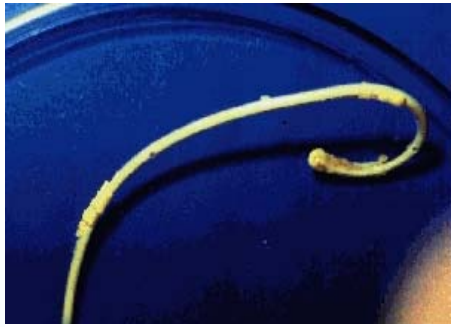
Conventional thermoplastic catheter material example:
100% polymer

Conventional thermoplastic catheter material example:
80% polymer / 20% radio-pacifier

Hydrophilic polyurethane example:
60% polymer, 20% radio-pacifier,
20% water

pAguamedicina example:

10% polymer, 90% water
Radio-pacifier, negligible



Typical urological short term implant complication

Polyurethane sample 10 X magnification of surface

(**typical encrustation**)

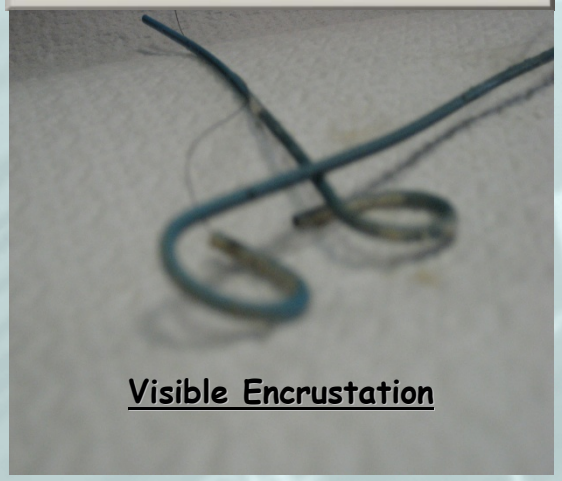
Bio-compatibility (In-vitro) of catheter materials

Potential to eliminate bio-film formation & encrustation.

7 days submersion in **human urine** at 98°F

Typically competitive sample

Encrustation & Bio-film staining (stent was initially white)



Visible Encrustation

pAguamedicina stent sample

pAguamedicina sample

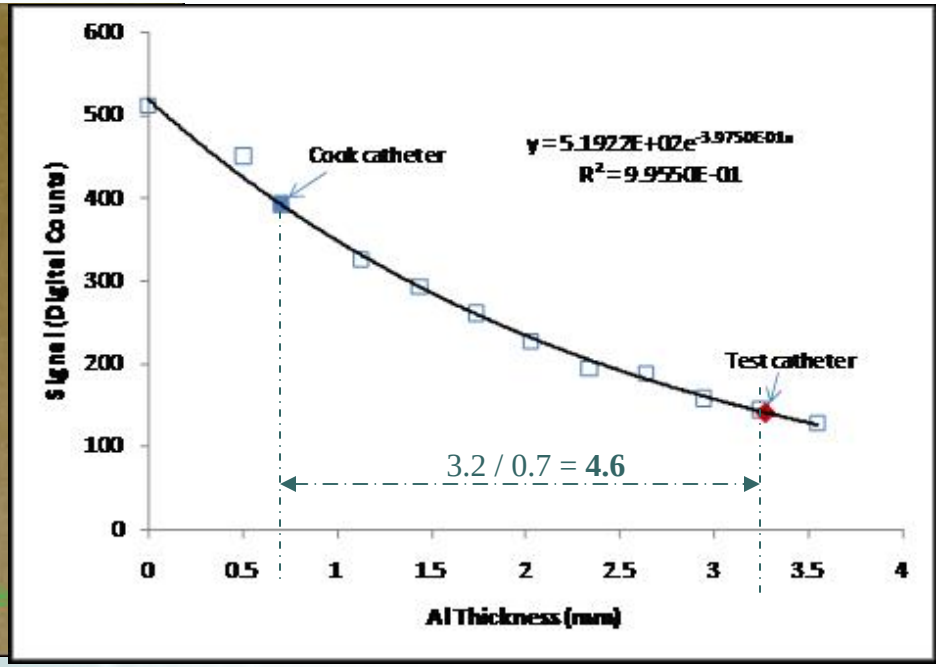
10 X magnification of surface (**no sign of encrustation)**

Bio-compatibility (continued)

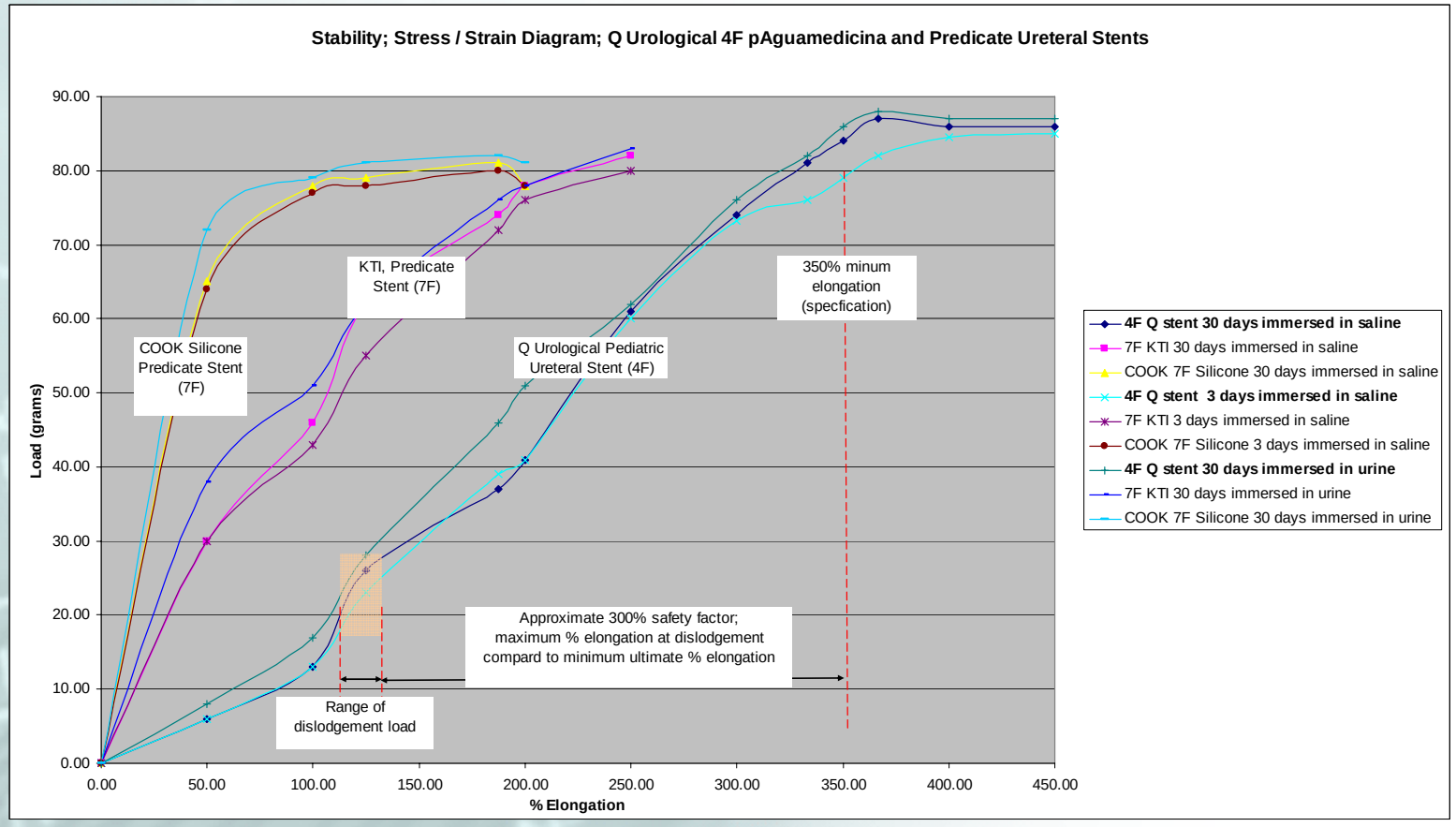
ISO / FDA / CE requirements		
Test description / name	**ISO ref. #**	**Score**
Cytotoxicity using 1X Minimal Essential media.	10993: **5**	**PASS**: No evidence of cell lysis or toxicity was observed.
Muscle implantation (**4 week**) study with Histo-pathology	10993: **6**	**PASS:**
Intracutaneous Study, 0.9% **Sodium Chloride** Solution Extract	10993: **10**	**PASS**: There was **no erythema** or **no edema** from extract tested injected intracutaneously into rabbits.
Intracutaneous Study, **Sesame Oil** NF Extract		
Systemic Toxicity Study; 0.9% **Sodium Chloride** Solution Extract	10993: **11**	**PASS**: There was **no mortality or evidence of systemic toxicity** with either extract.
Systemic Toxicity Study; **Sesame Oil** NF Extract		
Genotoxicity, Bacterial Reverse Mutation Study, 0.9% Sodium Chloride Solution Extract	10993: **3**	**PASS:** Considered to be **non-mutagenic**
Genotoxicity, Mouse Lymphoma Assay, 0.9% Sodium Chloride Solution Extract		**PASS:**
Analytical testing		
Exhaustive Extraction, Lipophilic; Ethanol Extract; Non volatile residue		**PASS** All results were acceptable, (**PPB** levels of delectability)
Inductively Coupled Plasma **Spectroscopy**, Full Scan- **Extractable Metals**		
Determination of **Extractable Semi-Volatile Organic Compound** by GC / MS		
LC/MS Chromatographic **Screen for Extracts**		

Radiopacity

(Can also be engineered for visibility in CT, MR and Ultrasound environments)

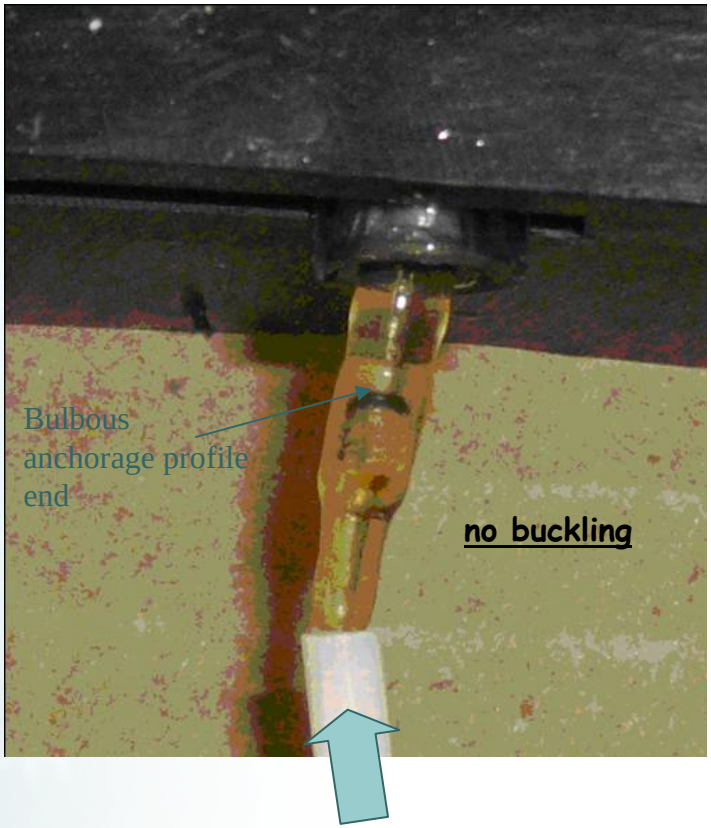


Mechanical Characteristics



Comparative column strength

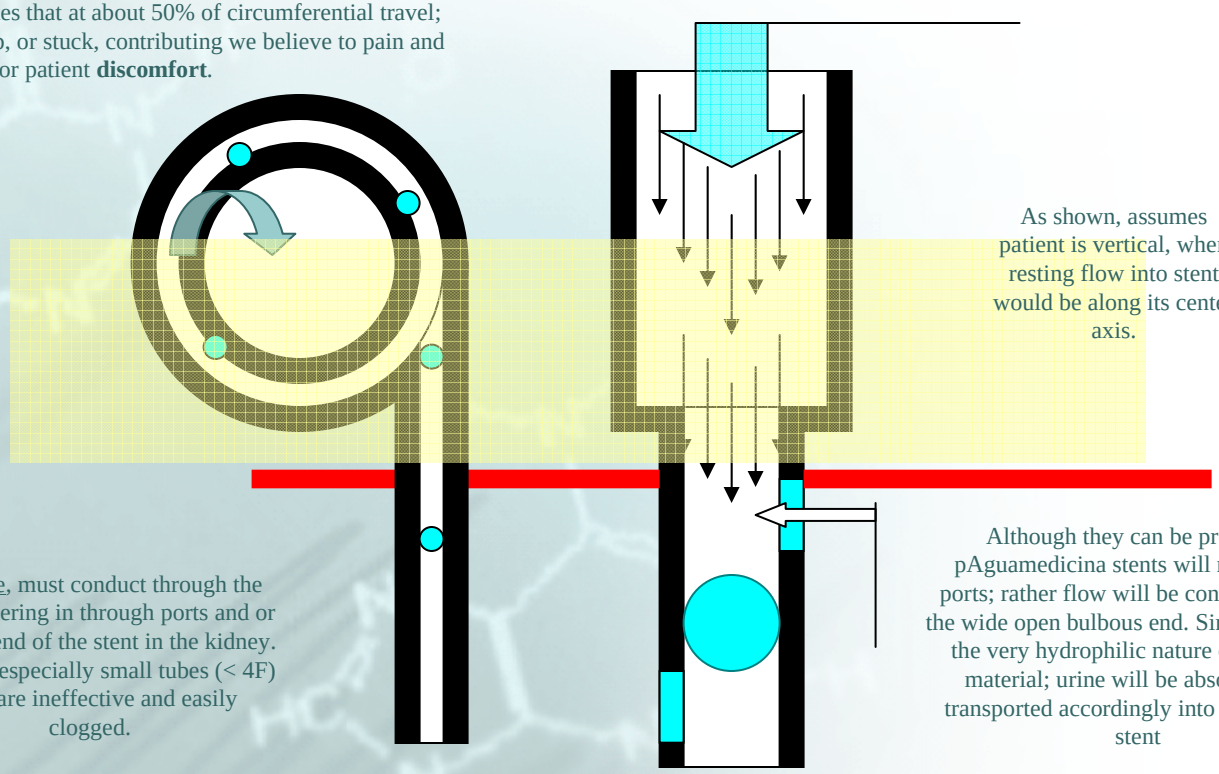
Push-ability



Anchorage details

Conventional pigtail anchorage end;

whereby loop diameter * 3.14 = anchorage compliance; essentially the unwinding or the loop due to peristaltic and or anatomic movement. However testing indicates that at about 50% of circumferential travel; pigtail becomes hung-up, or stuck, contributing we believe to pain and or patient **discomfort**.



As shown, assumes patient is vertical, when resting flow into stent would be along its center axis.

Drainage, must conduct through the lumen entering in through ports and or the open end of the stent in the kidney. However especially small tubes (< 4F) ports are ineffective and easily clogged.

Although they can be provided, pAguamedicina stents will not require ports; rather flow will be conducted form the wide open bulbous end. Similarly due to the very hydrophilic nature of the stent material; urine will be absorbed and transported accordingly into through the stent

Dynamic analysis

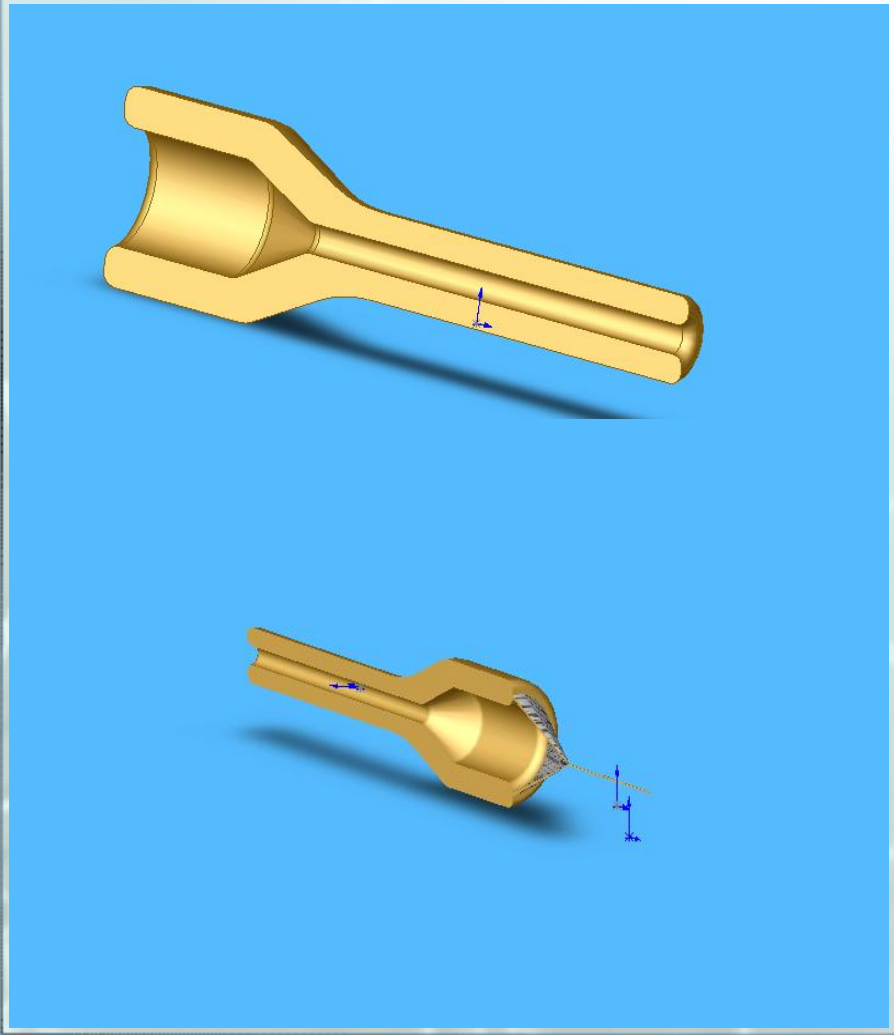
Package

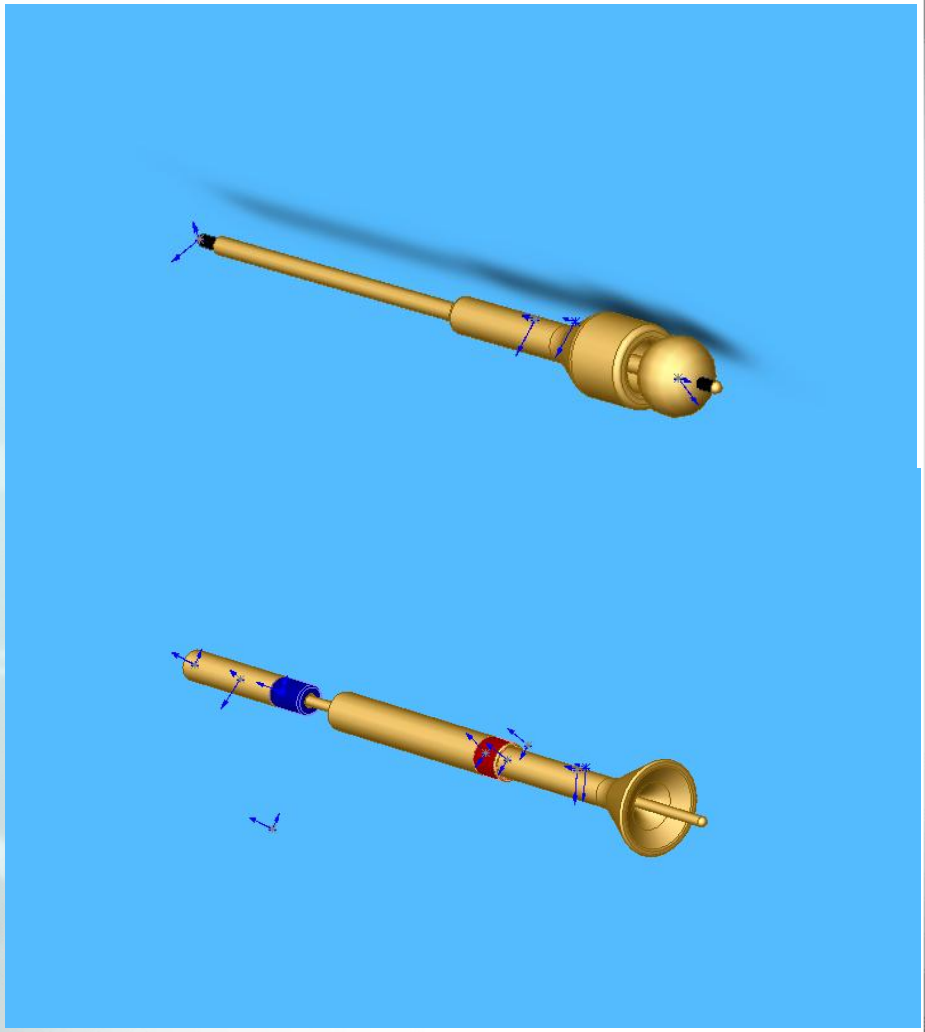
Product Design Opportunity

Shapes, profiles, geometry, Hybrids

(Can incorporate shape memory, be used as a unique device material or combined as a hybrid, with other materials or components)

Currently approved: **510K cleared 01/20/2010 pAguamedicina™ Structural Hydrogel Pediatric Ureteral Stent,**





Summary of Expectations

Very biocompatible medical device material

Instantly slippery when saturated with saline, water or bodily fluids

Reduced coefficients of friction when sliding coaxially over or against dissimilar materials.

Can be saturated with almost any aqueous media, exhibiting delivery and absorption gradients; remaining stable and impervious to most solvents.

Saturated in aqueous solutions (pH: 5.5 to 7.0) exhibits (about 20A Shore durometer); however can be engineered to exhibit specific characteristics.

Can not ETO or steam sterilize; however Radiation sterilization method **does not** effect polymer characteristics.