# Reduces potential fluid leakage

in pediatric applications



### **Increased Resistance to** Leakage Through Graft Wall

Previous Graft - Water Leakage at 500 mmHg



Modified Graft - Water Leakage at 500 mmHg



Pressure at which sustained leakage begins

**Previous Graft Modified Graft** > 1500 mmHg 290 mmHg (Benchtop Testing with Water)

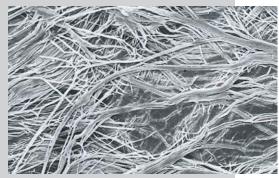
For more than 30 years GORE-TEX® Vascular Grafts have provided the performance that pediatric cardiac surgeons trust for use in the modified Blalock-Taussig shunt. Now we have taken that one step further.

### **Limited Clinical Evaluation Indicates Potential Decrease** in Serous Fluid Leakage with Modified Shunt

Japanese Clinical Evaluation:

- Evaluating centers historically experienced up to 33% incidence of fluid leakage
- 20 implants to palliate congenital defects
- Chest X-ray at discharge and one month
- No ultrafiltration at time of implant
- No evidence of seroma formation at one month follow-up





SEM of Previous ePTFE Reinforcing Film Photomicrograph 1000x Magnification 10 Microns



SEM of Modified ePTFE Reinforcing Film Photomicrograph 1000x Magnification 10 Microns



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### Modification to the GORE-TEX® Vascular Grafts Configured for Pediatric Shunts

- No change to base tube or flow surface
- Modified reinforcing film:
  - Same ePTFE as previous reinforcing film
  - Reinforcing film has a smaller pore size

CATALOGUE	INTERNAL	TOTAL
Number	DIAMETER	GRAFT LENGTH
ST03005A	3 mm	5 cm
ST03010A	3 mm	10 cm
ST03015A	3 mm	15 cm
VT03010LA	3 mm	10 cm
ST35005A	3.5 mm	5 cm
ST35010A	3.5 mm	10 cm
ST35015A	3.5 mm	15 cm
VT35005LA	3.5 mm	5 cm
VT35010LA	3.5 mm	10 cm
ST04010A	4 mm	10 cm
ST04015A	4 mm	15 cm
VT04010LA	4 mm	10 cm
ST05010A	5 mm	10 cm
ST05015A	5 mm	15 cm
VT05010LA	5 mm	10 cm