Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

## Healing Chronic, Ischemic, Infected Saphenous Vein Harvest Sites in the Legs with Silver Plated Cloth and Allograft Dermal Regenerative Matrix

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Unhealed coronary artery bypass graft (CABG) harvest sites may occur in the legs following saphenous vein removal. There are about 500,000 CABG procedures (U.S.A.) yearly, and the reported incidence of wound complications is up to 24% with half of these wounds becoming chronic, indicating they would benefit from wound care.

15 consecutive diabetic patients referred to the wound care program for chronic limb threatening wounds from vein graft harvest were treated. Wounds were present for 90 days or more and had been in other wound care programs for 60 days or more, without progression of healing. Previous treatments had consisted of debridement, wound vacuum assisted closure, cryopreserved human fibroblast-derived dermal substitute grafts and electrical stimulation. Bacteria identical to that resulting in at least one prior episode of documented sepsis in each patient (Av.= one episode, range 1-3 episodes of sepsis) and twelve of these were MRSA or VRE.

Wounds were debrided surgically and by maintenance sharp debridement. Wound infections (5) were treated with systemic antibiotics. Ischemia (15, ankle brachial index 0.3 to 0.8) was treated with cilostazol\*(14) and angioplasty (10). None of the limbs involved were anatomically amenable to bypass surgery.

Subsequently, specially prepared allografts\*\* were applied to the debrided leg wounds under silver plated cloth\*\*\*and left in place for 3 weeks. At that time another application was performed. Moisture was maintained with applications of mineral oil over the silver cloth.

10/15of these recalcitrant wounds were subsequently healed, three had amputations and two required flaps (one myocutaneous and one cutaneous). The three amputations occurred in the three patients with the lowest ABI indeces and had renal failure. There were no further episodes of sepsis.

Use of silver cloth and dermal grafts appear to be a reasonable approach to healing recalcitrant, chronic vein harvest donor sites in diabetic ischemic wounds.

- \* Pletal™, Otsuka Corp., New York, N.Y.
- \*\* Alloderm™ fenestrated, Life Cell Corporation, Branchburg, New Jersey 08876
- \*\* Silverlon™, Argentum Inc., Willowbrook, Illinois 60527



Left before and after one application of Allograft and Silver plated cloth (21 days)

Patient Population	
Age	16-80 years
Male	10
Female	5
Diabetes	15
Tobacco use	7
Renal failure	5
lschemia ABI between 0.3 and 0.8	15
Wound areas	AV=10cc Range 5-36cc

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