

K951592

510(k) Summary of Safety and Effectiveness

General Information

Manufacturer: Duxbury Scientific, Inc.  
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Hingham, MA 02043

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Device Name

Proprietary Name: *Betatrans*<sup>TM</sup> Orthopaedic Autotransfusion System

Classification Name: Autotransfusion Apparatus

Predicate Devices

Stryker® ConstaVac<sup>TM</sup> Blood Conservation System  
Solcotrans® Plus (Daval®, a division of C.R. Bard, Inc.)  
Gish Medical Blood Recovery/Autotransfusion system  
Gish Medical Orthofusor  
Boeringer Laboratories AutoVac

Product Description

The *Betatrans*<sup>TM</sup> Orthopaedic Autotransfusion System consists of a stainless steel trocar and PVC wound drain available in 1/8", 3/16 and 1/4" ID sizes the line is connected to a PVC blood collection line with a universal Y connector and pinch clamp which connects to a 800ml PETG blood collection chamber with integral 260 micron gross clot pre-filter and either one or two female halves of a patented "Duxbury Connector" bonded to the bottom of the chamber. one or two preconnected sterile 800ml blood bag.

A bag contains at it's top a male "Duxbury Connector" and a transfusion port. A safety cap covers the transfusion port and is available for use as a cover for the male connector once separated from the collection chamber. The bags male and female connector are shipped in a locked position. In this position a valve is

located in each half of the connector remains closed, preventing fluid or air to pass in either direction.

A vacuum tube assembly consisting of a 0.45 micron bacterial air filter, one way outflow valve, pinch clamp, and a five in one suction connector for venting of the chamber, as air is displaced by incoming blood. A vent cap assembly with a tethered screw on cap, one way inflow valve and a 0.45 micron filter to allow venting of the chamber during transfer of blood to the blood bag(s).

### Substantial Equivalence

The *Betatrons*<sup>TM</sup> Orthopaedic Autotransfusion System is substantially equivalent to the Stryker® ConstaVac<sup>TM</sup> Blood Collection System, Davol®'s Solcotrans® Plus, Gish Medical Orthofusor and Boehringer Laboratories AutoVac in that they are designed with the same design principles, made of the same or similar materials, and have the same indication and contraindications for use.

### Indications for Use

To collect and infuse blood lost by a patient due to orthopaedic surgery..

### Summary of Studies

Performance testing results confirm the subject device conformance to the ANSI/AAMI Standard AT6-199 and FDA modified ISO 10993-1:1992(E) biocompatibility matrix. The product labeling conforms to 15th Edition AABB Standard. Sterilization was performed using AAMI's "Guide to Industrial Sterilization", 1991:Method 3. and gamma irradiation. Studies using aged, sterile units included pressure and vacuum challenges, biocompatibility testing, helium leak test, microbial challenge to the product and connector, and function hemocompatibility testing. Hemocompatibility studies compared a series of blood and blood cell parameters using aged, pooled human blood versus values samples obtained prior to collection and predicate devices. The testing indicates the *BetaTrans* product meets applicable standards, is biocompatible, equal to or better than the predicate device, and performs according to design specifications.

<p><b>BetaTrans Biocompatibility Summary Test</b>  <b>Special Immersion Test- Duxbury Valve</b></p>	<p><b>Results</b>  <b>No growth of challenge organism in connector</b></p>
<p><b>Bacterial EndoToxin Testing</b></p>	<p><b>Less than 0.03 EU/ml or less than 1.2 EU/Device found</b></p>
<p><b>MEM Elution L929 Cytotoxicity Test</b></p>	<p><b>No reaction greater than grade 2</b></p>
<p><b>U.S.P. Intracutaneous Test</b></p>	<p><b>Meets the requirement of the test. No mean skin reactions greater than a difference of 1.0 from the blank.</b></p>
<p><b>U.S.P. Systemic Injection Test</b></p>	<p><b>Meets the requirement of the test. No significant difference from the test group to the control group.</b></p>
<p><b>Ames Mutagenicity Test</b></p>	<p><b>The BetaTrans Unit was not mutagenic against any of the tester strains either directly or following metabolic activation with S9(M+)</b></p>
<p><b>Guinea Pig Maximization (Kligman) Test</b></p>	<p><b>Skin Reactions were not observed in the guinea pigs treated with the BetaTrans Unit</b></p>
<p><b>U.S.P. Subchronic Toxicity Test</b></p>	<p><b>The BetaTrans Unit did not show any discernable toxicity in the systemic portion of the study after 33 days.</b></p>
<p><b>Hemocompatibility (Performance Test)</b></p>	<p><b>All blood and blood cell parameters pretest were equivalent post test and to the predicate device</b></p>

**Betatrans Component Biocompatibility Summary**

<b>Component</b>	<b>Material</b>	<b>Test</b>	<b>Results</b>
<b>Y-Connector</b>	<b>Plastisol</b>	<b>USP Class VI</b>	<b>Negative</b>
<b>Blood Line</b>	<b>Polyvinyl Chloride</b>	<b>USP Class VI</b>	<b>Negative</b>
<b>Blood Chamber</b>	<b>Eastman PETG 6763</b>	<b>Performed as part of Unit</b>	
<b>Gross Blood Filter</b>	<b>K-Resin &amp; Polyester</b>	<b>USP Class VI</b>	<b>Negative</b>
<b>Adjustable Strap</b>	<b>Nylon</b>	<b>N/A</b>	<b>No Patient or Blood Contact</b>
<b>Vernay Duckbill</b>	<b>Elastomeric &amp; Acrylic</b>	<b>USP VI L929 cytotoxicity USP Physiochemical Hemolysis</b>	<b>Negative Negative Negative Negative</b>
<b>Duxbury Connector</b>	<b>ABS &amp; Polycarbonate</b>	<b>USP Class VI</b>	<b>Negative</b>
<b>Blood Bags</b>	<b>PVC Film</b>	<b>USP Class VI</b>	<b>Negative</b>

**Performance Testing Physical**

**Test**

**Leak Test- 200mmHg Pressure**

**Leak Test- 100mmHg Vacuum**

**Particulates**

**Results**

**No Leaks were observed**

**No Leaks were observed**

**Meets AAMI AT6 Standard**

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