

An IRS qualified non-profit
501 C (3) charitable public
benefit corporation

February 7, 2007

Special points of interest:

- Comprehensive inventory management
- Diverse repository expertise
- Professional worldwide logistics
- 24 hour customer care
- Quality and security
- Full regulatory compliance

We're on the web!
www.catransplant.org

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Major investment in Quality Systems for Autologous Tissue

At California Transplant Services, Inc., we have invested several million dollars to ensure the equipment and facility that store your irreplaceable autologous tissue grafts are as advanced as the company that built it. Our headquarters located in Carlsbad, California, was designed specifically to serve as a world-class human tissue preservation laboratory complying with strict 21 CFR Part 1271 (Good Tissue Practices) regulations and 21 CFR Part 11. From our commitment to using only Thermo Electron ULT - 86C freezers to our

comprehensive security access program, the physical assets of our facility reflect the technical expertise, strict standard operating procedures (SOPs) and quality assurance measures we utilize to give your autologous human tissue specimens and samples optimum care from the moment they arrive at our manufacturing and storage distribution.

May 25, 2005 was the implementation date of 21 CFR 1271 which includes requirements for a Quality Program to be in place in all federally registered hu-

man tissue banks. These new regulations include reporting requirements for deviations and adverse reactions, validation of procedures involving the processing of tissue and donor eligibility requirements.



Safety and Security

Every aspect of California Transplant Services, Inc.'s headquarters' structure—inside and out—was designed with security and safety in mind. We chose an all-concrete structure that provides maximum resistance

against any natural disaster built to strict California earthquake standards. The layout of our shipping, receiving, administrative and storage areas was designed for maximum surveillance and provides minimal points of

entry. The building incorporates card-controlled access to critical zones, preventing unauthorized interaction with samples. In addition our security patrolled facility features 24-hour video (continued on page 2)

Thermo-Electron approved as key supplier

We implemented a proprietary inventory management system that provides the best functionality and in-depth audit trail documentation available. This commitment to excellence extends into California Transplant Services, Inc.'s decision to standardize our facility with Thermo-Electron ULT -86C freezers. Each

modern freezer is individually locked and supported by a back-up CO2 system. Integrated temperature monitors verify each freezer's temperature and record the data. If a temperature excursion exceeds allowable limits, automatic alarms alert on-site and off-site staff immediately, for instant response. By stan-

standardizing our facility with Thermo-Forma ULT -86C freezers, we ensure that your autologous tissue specimens can be seamlessly transferred to an identical freezer and stored exactly according our SOP's. Your autologous tissue specimens will never be stored or monitored by second-hand, refurbished equipment.



Safety and Security (continued from page 1)

surveillance, burglar alarm, and fire suppression systems, with protection of critical data storage by an Intergen fire suppression system, so critical data records are not lost. Both on-site and off-site staff receives immediate alerts in the event of a security breach. Redundancy in the freezer monitoring system is provided by



SDA Alarm, Inc. which has a UL listed 24 hour manned alarm monitoring center which will notify California Transplant Services, inc. staff in the event of equipment failure, power outage or

other unusual event requiring intervention. Even the alarm system has a proprietary back up cellular system for notification if the phone lines fail. We have redundant equipment monitoring and back up systems in place.

Major Trauma Centers participating

California Transplant Services, Inc. provides autologous tissue storage for major trauma centers for the storage of skull flaps from trauma (head injury) patients and any patient where the brain swelling prevents replacement of the skull bone. California Trans-

plant Services, Inc. has developed a kit utilized by hospitals which has a uniform system for the storage of the skull flap bone; once implemented at a hospital California Transplant Services, Inc. provides all training for hospital personnel involved in the

recovery of skull flaps and other autologous tissue. Some of the facilities utilizing our services include:

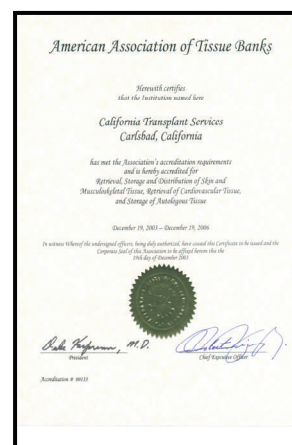
- Sharp Memorial Hospital —San Diego
- St. Frances Medical Center - Lynwood
- Good Samaritan Hospital - Los Angeles
- St. Jude Medical Center —Fullerton
- Kaiser Hospital - Anaheim
- San Francisco General Hospital
- University Medical Center - Las Vegas
- Sunrise Hospital Trauma Center - Las Vegas

Registered, Licensed and Accredited!

California Transplant Services, Inc. is **FDA-registered** as a storage facility for human cells, tissues and cellular and tissue based products (HCT/Ps). We also maintain accreditation issued by the **American Association of Tissue Banks (AATB)** to store and distribute autologous human tissue. Our annual registration with

the FDA is submitted each December, and our California State Tissue Bank License is renewed every October. Our SOPs were designed and are regularly updated by our full-time internal quality assurance experts. We follow the FDA guidelines as they pertain to cGTP (Current Good Tissue Practices), as well as

perform internal audits and regular updates of all maintenance logs, project and training files. California Transplant Services, Inc. has been licensed by the **California Department of Health Services** as a human tissue preservation laboratory since 1994.



Full Regulatory Compliance

California Transplant Services, Inc. is a TSA (Transportation Security Administration) certified known shipper. We provide our clients with all required packaging, labeling and documentation necessary for domestic inbound and outbound shipments.

We completely manage all the regulatory details required for infectious substances shipment as well as for foreign and US Customs. To ensure compliance with the most current requirements, we constantly monitor changing regulations relating to

transportation issues, including U.S. Customs, DOT and foreign countries. We are registered as a know shipper with United, US Airways, Delta, Southwest, and Sky West Airlines.

"We are registered as a know shipper with United, US Airways, Delta, Southwest, and Sky West Airlines."

Strong Proven Courier Relationships

California Transplant Services, Inc. maintains partnerships with leading worldwide couriers, including a strong, long-term business relationship with Federal Express. We are strategically located within minutes of the Carlsbad-Palomar Airport ser-

ved by United Airlines and US Airways and Federal Express' San Diego North County shipping hub. We also have relationships with DHL, UPS, ASAP! Express, Jet Delivery and many other couriers that all serve the Southern California area. Our

Carlsbad, California location is centrally located between San Diego and Los Angeles providing our clients with quick, cost-effective and efficient shipping options. We are within driving distance to 5 major international airports.

Our Mission

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We're on the web!
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California Transplant Services, Inc. is a non-profit full service eye and tissue bank offering physicians worldwide, the highest quality tissue for transplant available. California Transplant Services is accredited by the [American Association of Tissue Banks](#).

All surgical tissue is procured, processed and distributed in accordance with written SOP's reviewed by our Medical Director and following standards established by the [American Association of Tissue Banks](#) and guidelines established by the [U.S. Food & Drug Administration](#), [Eye Bank Association of America](#), U.S. Public Health Service and the [California Department of Health Services](#).

Among the tissues we provide are corneas for trauma and cornea blindness repair, bone for orthopedic and reconstructive surgery, skin for burn and trauma surgery, and tendons and ligaments for sports medicine.

California Transplant is proud to offer the only structured Autologous Tissue Storage (ATS) program in the United States for trauma and surgical patients.

California Transplant Services, Inc. is a California Non Profit Public Benefit Corporation and operates under a license from the State of California, Department of Health Services as a Human Tissue Preservation Laboratory (#CNC80141).

CTS and Novatek International join forces on LIMS Tissue Bank software

California Transplant Services, Inc. has entered into an agreement with Novatek International to adapt their **Advanced Quality Nova-LIMS** software system which is a 21 CFR Part 11 Compliant long-term solution that ensures we have centralized control and maintenance of all of our data handling software. It is a client/server product comprised of specialized functional modules such as the Environmental Monitoring, the Stability & Raw Mate-

rial Analyzer, Finished Product, Calibration and Preventive Maintenance, and Document Management System, audit and training Module. The key functions of this software will assist in

meeting the core GTP requirements and validation of existing and future processes. The first stages of implementation began the first week of October 2005.

