SynDaver™ Labs manufactures the world's most sophisticated synthetic human tissues and body parts. Our SynDaver™ Synthetic Human bleeds, breathes, and employs hundreds of replaceable muscles, bones, organs, and vessels which are made from materials that mimic the mechanical, thermal, and physico-chemical properties of live tissue. This validated technology is used to replace live animals, cadavers, and human patients in medical device studies, clinical training, and surgical simulation.

The SynDaver™ Synthetic Human (SSH) is the most elaborate and sophisticated surgical simulator ever devised. The SSH is a synthetic physical representation of typical human anatomy, including skin with fat and fascia planes, every bone, muscle, tendon, and ligament in the body, a functioning respiratory system including trachea, lungs, and diaphragm, a complete digestive tract from the esophagus to rectum, the visceral organs (kidneys, liver, gall bladder, pancreas, spleen) a circulatory system with heart and coronary arteries, aorta, vena cava, and the primary arterial and venous trunks leading to the extremities.

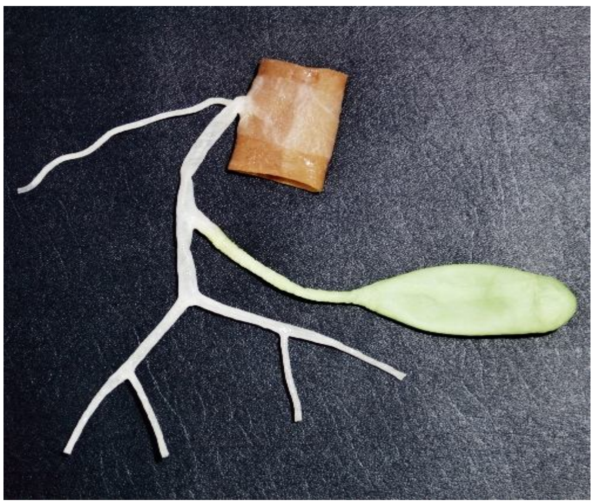
TENDENOUS SKULL

The SSH represents the pinnacle of hands-on surgical simulation, and is made like a 3D jigsaw puzzle:**Every muscle, bone, organ, and vascular component is individually removable and replaceable.**

The model pumps heated synthetic blood (pulsed flow away from the heart and drainage toward the heart), is capable of insufflation, and can be intubated and placed on a ventilator. Individual tissues of construction have been validated by SynDaver™ Labs over the last decade to mimic the mechanical and physico-chemical properties of the relevant living tissue.

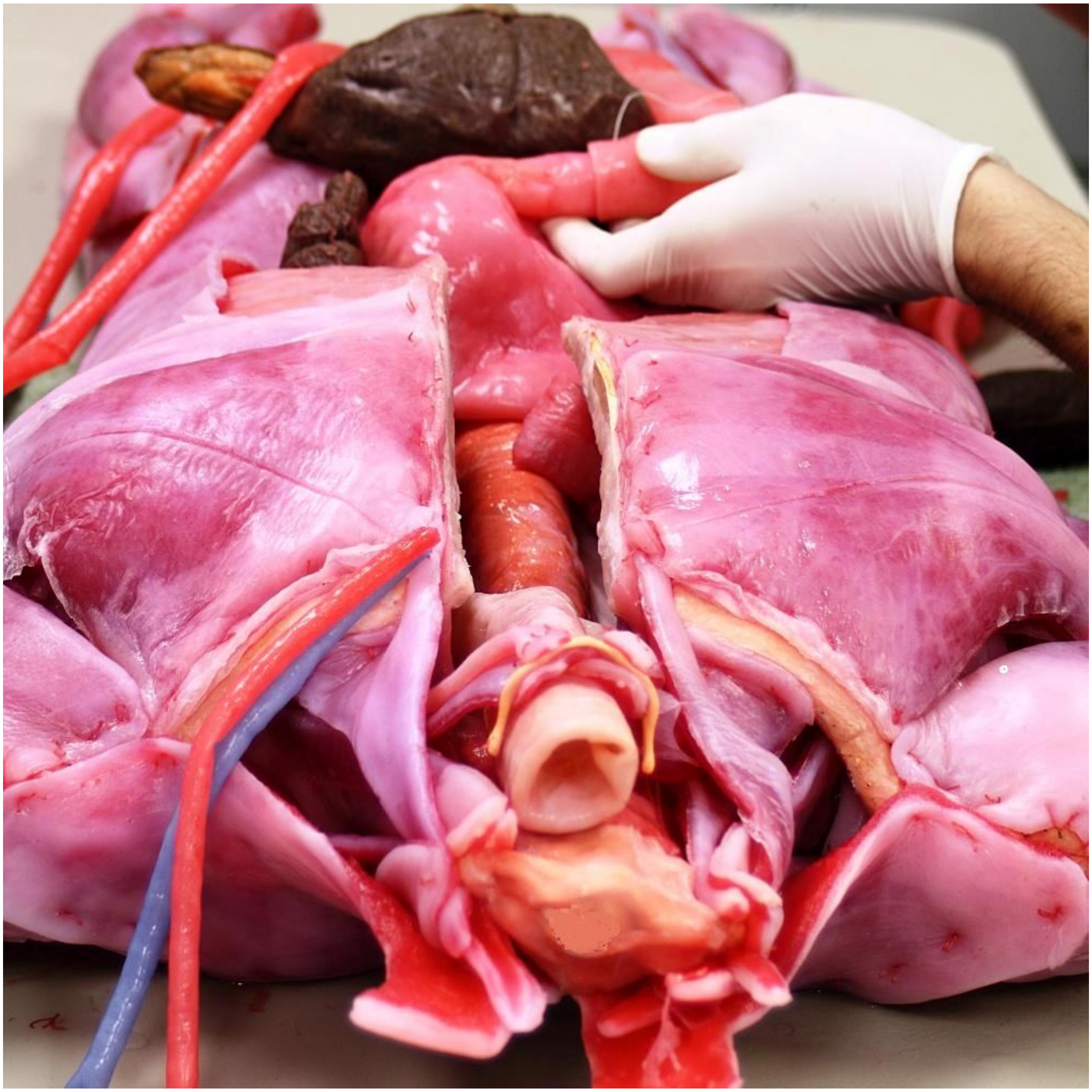
Additional soft tissues included but not shown include full-body fascia, subcutaneous fat, and skin. ALL muscles, bones, organs, and vascular components are separately removable and replaceable to allow onsite servicing and upgrades.

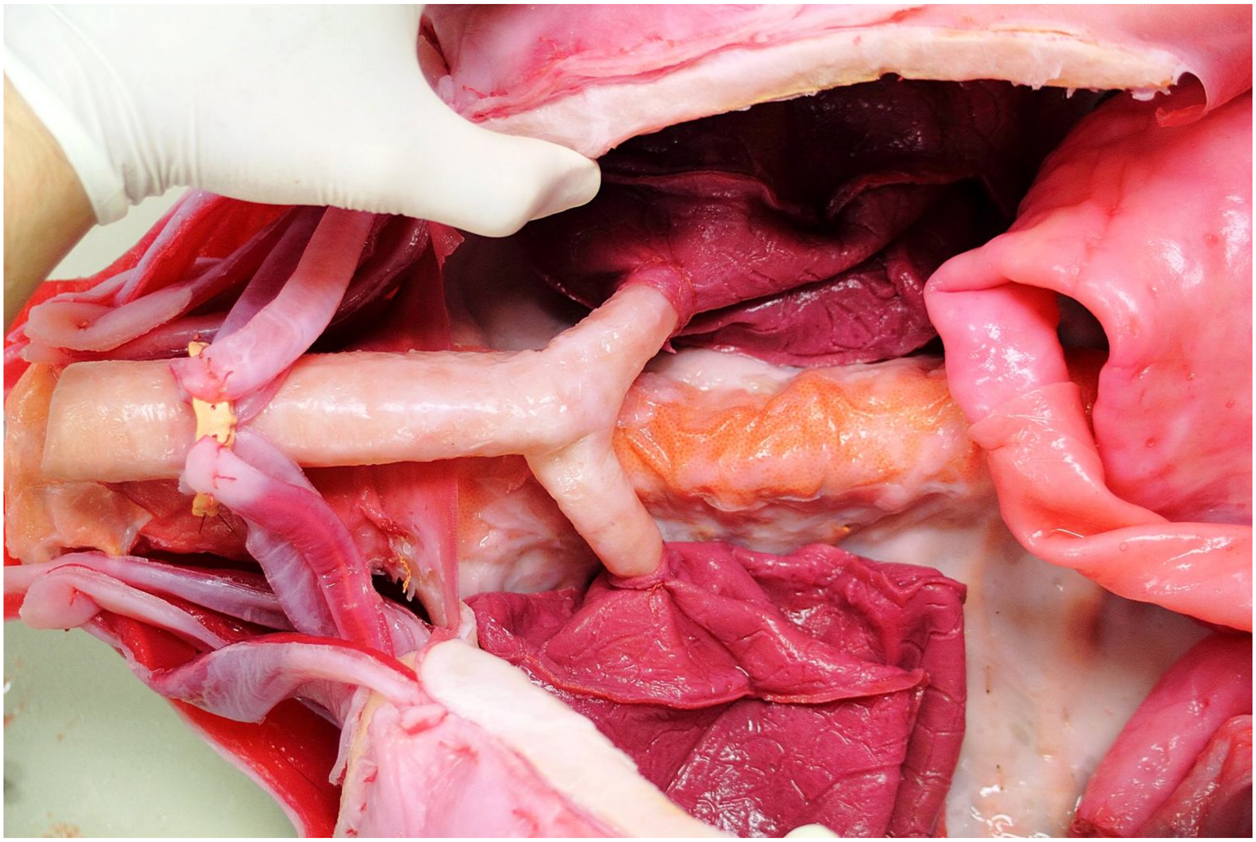
Simple Billiary System

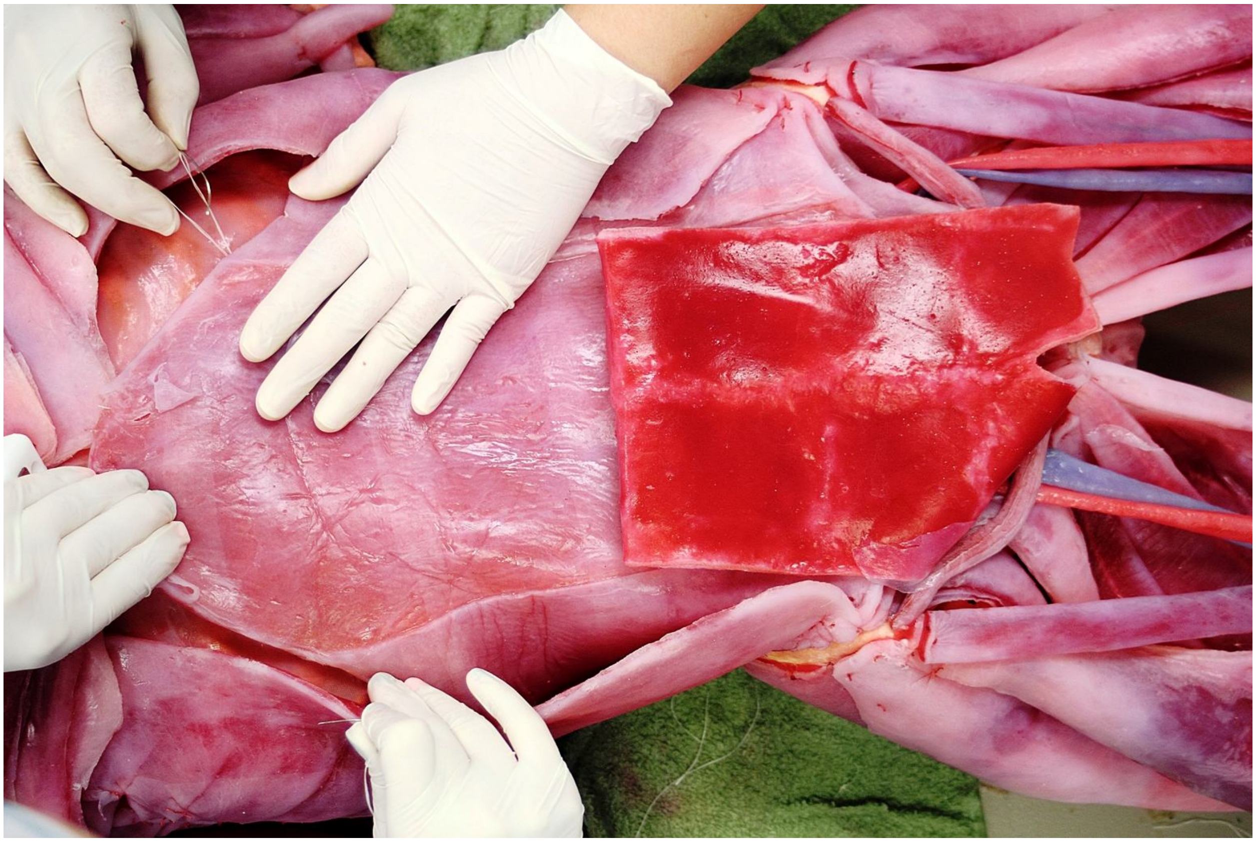


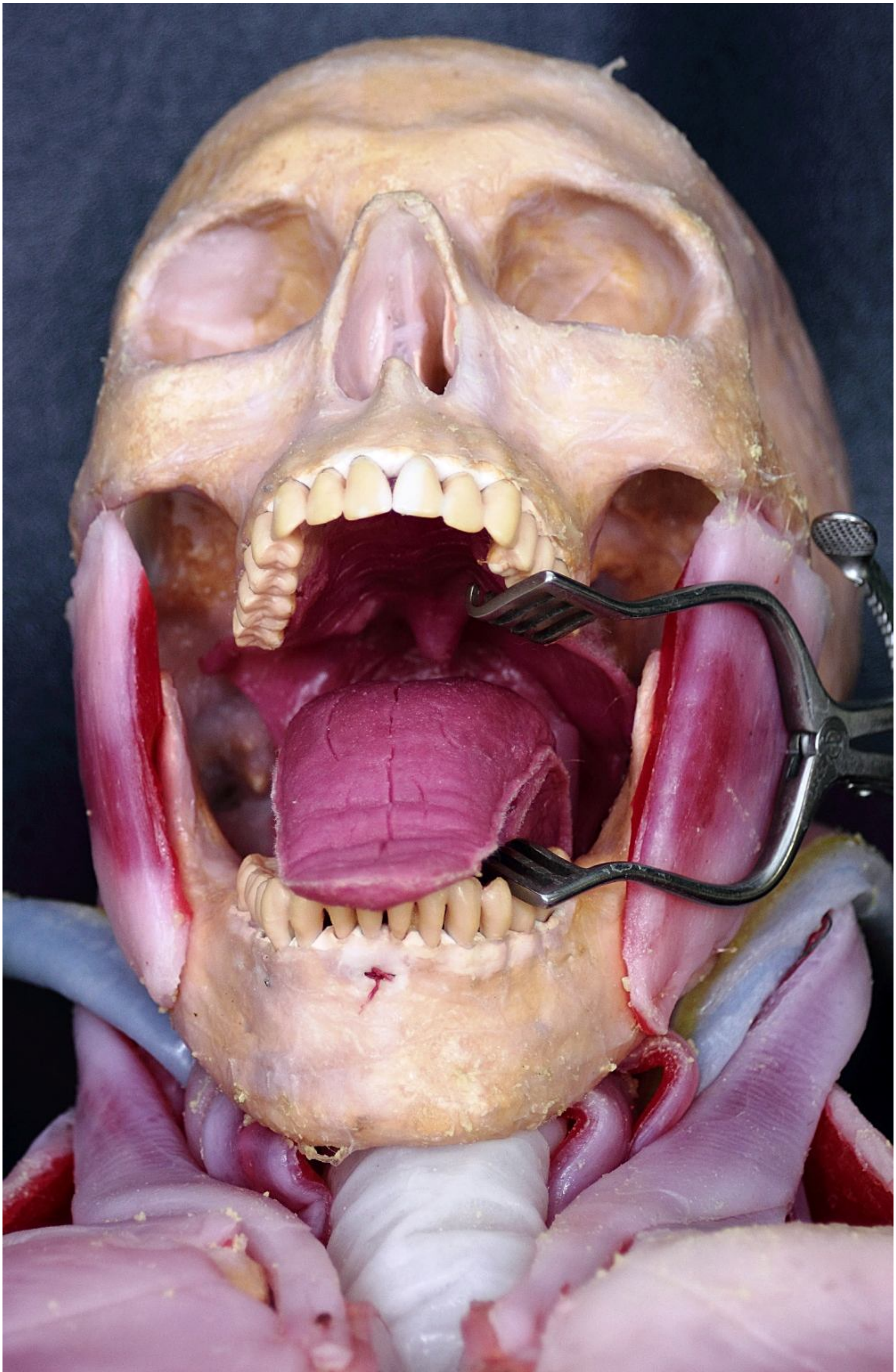
FEMALE TORSO

Female Torso Musculature









The system includes a storage container, stainless-steel procedure cart, heart pump with separate venous and arterial circuits, and all required plumbing.

Procedures tested to date include **coronary stent placement with fluoroscopy, chest tube placement, tracheotomy, cricothyroidotomy, carotid endartarectomy, infusion port placement, central line placement with ultrasound, angioplasty, appendectomy, embolectomy, and femoral cutdown with closure device.**

Product includes one full year of anatomy upgrades and tissue improvements. The system is also covered by a three-year warranty covering manufacturing defects.

Benefits

The synthetic human tissues and body parts produced by SynDaver™ Labs have a number of characteristics that make them useful for both medical device development testing and surgical simulation.

First, since these products are designed to respond to physical stimulus in a fashion similar to the target (human or animal) anatomy, device performance in the model may be used to predict performance under actual use conditions.

Second, in most cases the device-interfacing portion of the model may be removed for quasi-histological examination, allowing the effect of the device on the target anatomy to be quantifiably measured. This feature is particularly important because it allows the potential for injury to be predicted.

Third, because the device interfacing portion of the model can be removed and replaced, a large number of tests can be performed under either identical or varying conditions as desired. This allows the generation of meaningful descriptive statistics on device performance and the execution of designed experiments, both of which are nearly impossible with live animals or cadavers. **Fourth**, the models may be fitted with integral pumps, heaters, and other accessories to more accurately simulate the physical aspects of actual use conditions. **Finally**, the models may be equipped with sensors that allow the measurement of pressure, flow, strain, or other characteristics in the target anatomy.

Synthetic Human Tissues

SynDaver™ Labs' products may be substituted for traditional models in such tests by nature of their similarity to the actual use environment. This resemblance is characterized by a matching of mechanical, physical, and chemical properties, geometry, and organ-to-organ interaction. On the simplest level, individual synthetic organs (rectus femoris muscle, small intestine, abdominal aorta, etc) are constructed so that they replicate the geometry (shape, diameter, wall thickness etc) of a particular portion of the target anatomy. In addition, the individual synthetic tissue analogs used to fabricate these components are formulated so that they exhibit chemical and physical properties (water, fiber, and salt content, strength or modulus in shear, coefficient of static or dynamic friction, surface energy, dielectric properties, heat capacity, porosity, etc) that mimic the properties of the target tissue. Finally, the model components are assembled in such a way that the interaction between adjacent components is similar to that expected in the target tissue. That is, the body part is designed so that interfacial properties such as the coefficient of dynamic friction (inter-organ) and mechanical attachments mimic those exhibited in the target anatomy.

In order to design these synthetic body parts, the anatomy to be simulated must be conceptually divided into discrete sections that will form the basis of the model. For example, a very simple model of the thoracic aorta might be separated into two parts; the first consisting of the artery itself and the second of the surrounding tissues. At least two (and possibly many more) tissue analogs would then be designed for the fabrication of this model. In this case, one tissue analog would be required for the artery component and the other would be used to construct the supporting tissue component. Of course, in practice models require more than two tissue components to accurately simulate the response of the target anatomy, and each of these components would typically employ three or more tissue analogs. SynDaver™ elastic arteries, for example, employ separate tissue analogs for intima, media, and adventitia, and each of these layers are individually comprised of multiple materials.

Synthetic Tissue Analogs

SynDaver™ Labs' synthetic human tissues are designed to mimic one or more properties of a specific target tissue, and in order to develop each analog two sets of design inputs (modeled properties and data source) must be defined. The modeled properties are determined by prioritizing the chemical, physical, mechanical, and other properties that the analog must mimic, and strictly speaking these may vary depending on the type of device being tested or procedure being simulated, the target anatomy, and the objective of the exercise. For example, if one objective is to determine the intimal damage caused by a device tracking through the femoral artery, abrasion resistance would be included in the target list for the tissue analog. In addition, if it was also desired to simulate the tendency of the device to penetrate the artery then penetration resistance or shear strength of the shell (a related mechanical property) would be included in the list as well. Any number of properties may be added to this list. However, as the number of modeled properties grows it becomes progressively more difficult to simultaneously satisfy all of the design requirements. In fact, if a particular tissue or organ must mimic more than three mechanical properties it will typically be necessary to employ multiple analogs to meet design requirements.

The data source which will form the design basis for the new tissue analogs must also be defined. First of all, it must be decided if the analogs will be formulated to mimic the properties of human tissues or animal tissues (either living or dead). Once this question is answered, the relevant data may either be drawn from the literature or generated directly by performing the appropriate tests on tissue samples. However, it should be noted that vastly superior results will always be achieved by performing the relevant tests directly. The results of mechanical-physical tests are highly dependent on test conditions, and controlling the test gives the designer control over such conditions. More importantly however, it allows the candidate tissue analogs to be tested and subsequently validated under exactly the same conditions as the target tissue.

Model and Tissue Design

SynDaver™ and SynTissue™ brand products are designed to mimic specific human tissues and organs. The chemical, physical, mechanical, electrical, and optical properties these tissues mimic are based on data derived from testing **LIVING** human and non-human animal tissues. For the past decade we have performed relevant tests on live human lumenal (mouth, anus, vagina, etc) and skin tissues as well as living internal tissue from porcine models. The inclusion of porcine data in this data set is justified by the similarity between human and porcine tissues on the most basic level. For example, heart valves, arteries, fascia, and brain matter are similar in structure and function whether they are sourced from a human or porcine model, and this similarity is underscored by the established practice of porcine tissue transplantation into humans.

The drawbacks to using live animal data in this application are limited. The alternative (using live human tissue on a large scale) is not feasible for a number of reasons. First of all, the logistical and regulatory issues associated with testing live human tissues make collecting that type of data extremely difficult. While living human tissues are difficult to obtain in small quantities, they are impossible to obtain in statistically useful quantities, and there are very high regulatory hurdles that must be overcome in order to gain access to even a single live human subject. In addition, since the properties of any living tissue generally begin to change immediately after death, any samples harvested would need to be tested at the patient's death bed to minimize the lapse between harvest and data collection. This would would be impractical and prohibitively expensive given the high volume of testing required.

Of course, a great deal of information on the physical properties of human cadaveric tissue is available in the literature, and this data is one potential source for the design of tissue analogs. However, we do not use this type of data as design criteria unless specifically requested to do so by a client. First of all, the properties of living and dead tissues are different, with the discrepancy increasing with time elapsed after death and even more so after freezing or chemical preservation. In addition, employing data from literature would preclude control of tissue harvest, sample preparation, test design, and test method. This in turn would prevent validation of the resulting

Summary

SynDaver™ Labs' portfolio of products facilitates the generation of animal study quality performance data at a risk level normally associated with a bench top study. By employing this technology early in the development process, reliable feedback on device performance may be collected before erroneous assumptions are allowed to adversely affect the device design. This capability reduces the probability of costly late stage design changes, shortens the development timeline, and reduces the overall cost of bringing a product to market. As an added bonus, these models may be used in a standard laboratory by a technician, so the need to contract with research facilities, retain costly medical professionals, and absorb the risks associated with biohazard exposure are all eliminated. These synthetic human tissues, organs, and body parts are by far the most sophisticated and complete hands-on anatomical simulation tools available in the world today.