Birth Tissue Donation and Recovery
Lucina BioSciences, LLC

Birth Tissue
For the purposes of this paper, birth tissue refers to the placenta, umbilical cord and amniotic fluid. The recovery of birth tissue may include all or any combination of these components, depending on processing needs and the conditions of the Cesarean Section. The health and well-being of both mother and baby will always drive decisions concerning birth tissue donation and recovery.

Human amniotic membrane forms the lining of the fetal environment during gestation, separating the developing fetus from the mother in utero. The material used for surgical wound allografts is isolated from the membranous sac surrounding the infant to the point where it adjoins the placenta at the chorionic plate. On gross examination, the amniotic membrane is composed of a number of layers that can be seen and appreciated with simple handling and the naked eye. The material easily splits into an amnion layer and chorion layer, separated by a jelly-like, intermediate layer, apparent on separation of the 2 layers. The amnion or fetal side of the membrane is further coated with a layer of epithelial cells, which can be gently removed with simple cell scraping techniques to reveal a translucent underlying membrane. The amnion and chorion layers are in turn each composed of a basement membrane and stromal layer.1

Placental-derived Products
Amniotic membrane has been employed in the treatment of wounds for almost 100 years, beginning with early application of natural amniotic membrane obtained from labor and delivery to various types of burns and wounds. Amniotic membrane is rich in collagen and various growth factors that support the healing process to both improve wound closure and reduce scar formation. Unique properties of the material include the lack of immunologic markers, conferring an "immune privileged" status on the allografts; antibacterial properties; and the ability to reduce pain on application. The resurgence of interest in the use of amniotic membrane in a number of applications, including wound treatment, has occurred following improved techniques for preserving the natural membrane.1

In more recent years, application of this material has been extended to include wounds of other areas, including diabetic neurovascular ulcers, venous stasis ulcers, postoperative or posttraumatic chronic wounds, and postsurgical wound dehiscence. Today, dehydrated amniotic membrane has been extended to other potential uses as a reparative membrane in orthopedics, neurosurgery, periodontology, OB/GYN, general and reconstructive surgery, and a number of other medical fields.1 As a result, demand for birth tissue has grown well beyond the volumes that have been recovered by a limited number of agencies in the United States.
Birth Tissue Donation

Birth tissue recovery follows a similar pathway as organ and musculoskeletal tissue donation. Great care is taken to protect the privacy of the donor while following a strict set of guidelines to ensure safe and efficacious outcomes for the recipients of donated tissue. Steps include, but not limited to, informed consent, review of medical records, serological testing, culture swabbing for bioburden measurement, and sterile/aseptic techniques in handling of tissue. While there are no additional costs incurred by the birth mother, the laws that govern tissue donation dictate that no financial incentive can be offered if she chooses to donate.

It is important to note that, typically, birth tissue is recovered when a planned Cesarean Section is performed.

Donation and Recovery Process

The process of birth tissue recovery begins with the identification of a potential donor. Typically, the OB/GYN will introduce the concept to expectant mothers early in their pregnancy. Educational materials and consultation will be provided to ensure complete understanding of the process prior to choosing to donate. Informed consent and blood draw are required within 7 days of delivery.

Review of medical records is critical to safeguard recipients from potential cross-contamination. A medical and social history will be examined to determine inclusion/exclusion criteria for tissue donation. Medical records include culture results, anesthesiologist record, and other available relevant information. To protect the donor’s privacy, recovery agencies are required to adhere to strict HIPAA compliance in handling these records.

On the day of delivery, a certified technician is typically present in the OR suite to receive the birth tissue. Unless amniotic fluid is being captured, the procedure is performed exactly as if there was no donation occurring. The placenta will be removed and placed in a basin. Rather than discarding the tissue as medical waste, it will be handed to a recovery technician. If dissection of the specific layers of the placenta is required, it can be done either on a back table by the technician or it can be packaged and transferred to a recovery agency clean room to complete. The entire dissection takes approximately 15 minutes.

Should amniotic fluid be requested, the surgeon will take steps to safely capture a sufficient volume of fluid with minimal blood contamination. This procedure is only done when possible without any risk to the well-being of the baby. Amniotic fluid retrieval is not a mandatory condition for birth tissue donation or recovery.
Lucina BioSciences, LLC

Lucina was the Roman Goddess of childbirth. In ancient Rome, when women went into labor, Lucina was called upon to safeguard the mother. We have chosen Lucina as our company name to honor all birth mothers and share in the wish for the safe delivery of a healthy and happy child.

Lucina BioSciences, LLC was founded in Denver, Colorado in 2016 to address the amniotic membrane needs of the medical community. As a science-based organization, we strive to develop improvements in the tissue recovery process which may provide greater yields of higher quality tissue, giving us the ability to serve more recipients and improve outcomes.

Lucina BioSciences, LLC will be FDA registered and committed to following the strict practices of AATB Standards (American Association of Tissue Banking). We will be subjected to routine audits confirming that our operation maintains compliance with all regulatory and quality governing bodies.

Lucina’s Senior Management and Board can boast over 100 years of collective experience in this field, including organ, musculoskeletal, skin and cornea recovery, donor chart review, ascertainment of eligibility and suitability, serology and culture testing, and manufacturing, marketing and distribution of HCT/P (Human Cell and Tissue Products). Our recovery team will earn and maintain their CTBS (Certified Tissue Banking Specialist) to give our hospital partners confidence that our technicians are highly trained, skilled and professional while conducting business in the facility.

Lucina will provide to hospital staff development seminars and training on the donation process, recovery process, donor screening criteria, and uses of birth tissues as HCT/Ps. We will also offer educational materials to the birth mother to ensure that she may make a thoroughly informed decision to donate birth tissue. All supplies specific to tissue recovery will be the responsibility of Lucina.

In building a partnership in tissue donation, Lucina will ask the Hospital to facilitate access to OB/GYN practices and their maternity patients to educate physicians, staff and patients about the birth tissue donation process and conduct patient interviews to collect medical history and obtain consent. We will require access to patient medical records and diagnostic tests to determine eligibility and suitability. For purposes of planning efficiency, we will request access to the delivery schedule for those birth mothers who have chosen to donate.

In closing, Lucina BioSciences, LLC is committed to bringing a world-class birth tissue recovery program to the Denver area. Together with our hospital partners we will become industry leaders through ongoing research and development to continue to improve tissue and fluid recovery techniques and preservation methods that may increase viability for transplantation and enhance the clinical benefits of placental-derived products.

1 Scientific and Clinical Support for the Use of Dehydrated Amniotic Membrane in Wound Management
Donald E. Fetterolf, MD; and Robert J. Snyder, DPM, MSc, Wounds. 2014;24(10):299-307.