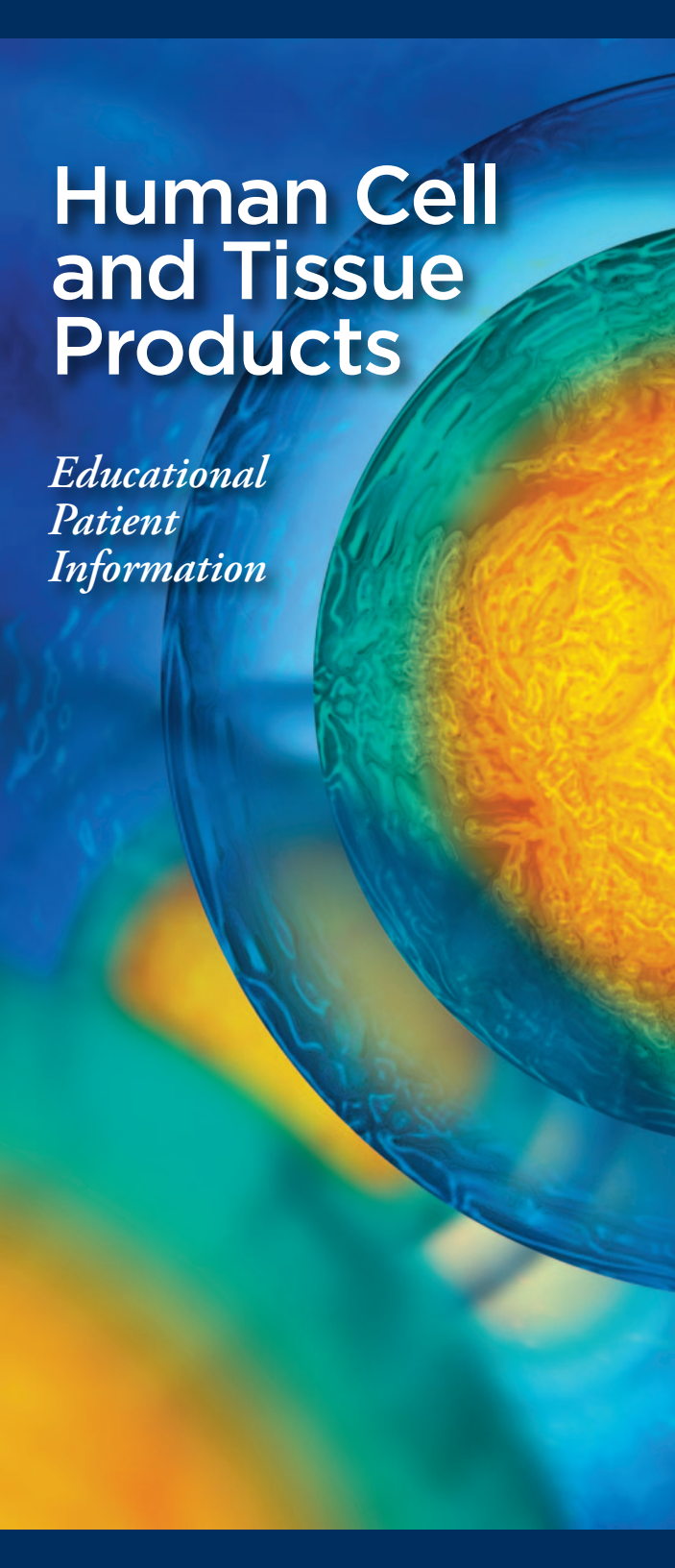
Human Cell and Tissue Products

Educational Patient Information



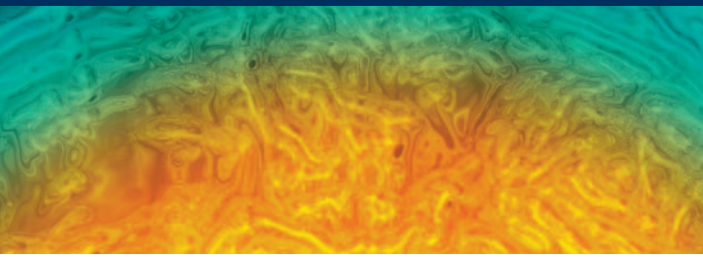
Human Cell and Tissue Products

What are Human Cell & Tissue Products?

Human cells, tissues, and cellular and tissue-based products (HCT/Ps) are products containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. The U.S. Food and Drug Administration (FDA) regulates an HCT/P solely through its authority in section 361 of the Public Health Service Act to prevent the transmission of communicable diseases — i.e., as a "361 product" rather than as a drug, biologic or medical device — if it meets all the following criteria in 21 CFR 1271.10(a):

- The HCT/P is minimally manipulated.
- The product is intended for homologous use only (meaning that the HCT/P performs the same function(s) in the recipient as in the donor).
- The HCT/P does not involve the combination of the cells or tissues with another article — except for water, crystalloids or a sterilizing, preserving or storage agent.
- The product does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function (which is satisfied if the product is acellular, meaning that it has no living cells).

HCT/Ps can be obtained from different sources (such as marrow, cord blood, peripheral blood, placental tissue) and have been used in a variety of therapeutic applications.[1]



We often refer to 361 HCT/Ps also as Human Allografts

A human allograft is a tissue from a human donor that is transplanted from one body to another. It is a general term that encompasses HCT/Ps, including 361 products. For example, placental allografts are naturally-derived tissues that may contain placental cells, extracellular matrix (ECM), and a complex array of regulatory cytokines that support tissue growth and modulating inflammation[2] in native placental tissue.[3] Placental allografts have been used for many years for various medical conditions.[4]

Many 361 HCT/Ps are Acellular

The term "acellular" generally refers to biological tissue material that lacks intact cells, is not divided into cells, or is devoid of cells. Consider that an acellular vaccine contains cellular material; however, the cells are not complete. In dentistry, acellular dermis is frequently used to address issues related to gingival tissue. Acellular dermis is a biomaterial that may be derived from animal or human tissue. This tissue is processed in such a way as to remove cells, while retaining some of the extracellular matrix (ECM). The ECM is the non-cellular component present within all tissues and organs.[3] Among other things, it provides physical scaffolding needed for structural support to surrounding cells.[5] Although the structure of an extracellular matrix depends to some extent on where the tissue originated, all ECMs contain proteoglycans, collagen fibers and multi-adhesive proteins.[6]

Some 361 HCT/Ps May Act as Scaffolds or Provide Supplemental Scaffolding Material

Many 361 HCT/Ps act as natural scaffolds to provide void volume for vascularization, support desirable cellular interactions to contribute to the formation of new functional tissue and add mechanical and shape stability to the tissue defect.[7] Some simply provide supplemental scaffolding materials that the body uses to form such scaffolds.

Tissue Regeneration, Healing, Repair, and Supplementation

Tissue regeneration is the natural process of replacing or restoring damaged or missing cells, tissues, organs, and even entire body parts to full function. Tissue regeneration and wound healing require an orchestrated integration of complex biological and molecular events, which include inflammation, proliferation, and remodeling. HCT/Ps are often used to supplement the cellular healing process by providing the building blocks for scaffolds used in healing, by retaining moisture needed for healing, by creating a barrier to protect the healing process, or by signaling to support the repair and regeneration process of damaged and injured tissue.[8]

Donated Tissue Screening: All HCT/Ps are required to be collected aseptically and tested prior to processing, and must be determined to be eligible for transplantation. Applicable donor testing and eligible standards include those prescribed by FDA regulations and those established by the American Association of Tissue Banking (AATB). The processes used have been developed to preserve the tissue characteristics for transplantation.

Tissue Processing and Sterilization: For 361 HCT/Ps, specific minimally manipulative tissue preparation and preservation methods are used to ensure the intrinsic cellular or tissue characteristics are retained. Many tissues remain in a hydrated form (as they are in normal physiology) and without loss of mechanical integrity. As a final processing step, many tissues are terminally sterilized. As with the implantation of any human tissue, there is always the possibility of an allergic reaction or transmission of a communicable disease.

FDA Regulation: Tissue allografts are regulated by FDA solely under the authority of section 361 of the Public Health Service (PHS) Act – not as drug, biologics, or medical devices – if they meet the four regulatory criteria described above: minimal manipulation, homologous use, being combined only with permitted articles, and not having systemic effect nor depending on the metabolic activity of live cells. These qualifying tissue allografts are exempt from FDA pre-market review, licensure, clearance, and approval from FDA.

Please consult your doctor to learn more and see if a tissue allograft is right for you. This brochure is intended to be educational and does not constitute medical advice. None of the statements in this brochure have been evaluated by the FDA.

References

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