PRODUCT USAGE WAIVER

PRODUCT CATEGORY:

Signature Cord, Signature Matrix, and Signature APatch (Signature Products) are intended by Signature Biologics to be regulated under 21 CFR 1271 and PHS section 361, in its entirety. As such we are providing a structural tissue product.

CRITERIA FOR USE:

An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;
(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
(3) The manufacture of 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, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
(4) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.

Signature Products are intended by Signature Biologics to only be put to a homologous use. Homologous use for Signature Cord (cushion), Signature Matrix (barrier), and Signature APatch (covering) products would **NEVER** include the following routes of administration: intravenous injection or infusion, aerosol inhalation, intraocular injection, or injection or infusion into the central nervous system. **Intravenous infusion or injection of Signature Products can cause life-threatening adverse evens or death.**

Signature Products cannot be represented as though they can be used for the following routes of administration: intravenous injection or infusion, aerosol inhalation, intraocular injection, or injection or infusion into the central nervous system.

Signature Products should only be used by a licensed healthcare professional. Please see the package insert for specific handling instructions. Vials are packaged inside two pouches and a plastic covering. Vial handling should be performed outside of the sterile field. Only the contents within the vial should be introduced into a sterile field. Wipe the vial with alcohol prior to opening. Signature Products should not be used on patients who are allergic to penicillin, streptomycin, amphotericin B or gentamicin.

I hereby consent Signature Biologics' Product Usage Waiver.
(PLEASE USE BLUE OR BLACK INK PEN ONLY)

Healthcare Professional's (HCP) Name	*HCP's Signature*	*Date*
HCP's NPI Number	*Street Address*	*City/ State/ Zip Code*