

Catalog Number: 3535

Product Description: Synthemax II – SC Substrate

Component Materials:

Polymer - Proprietary Peptide Acrylate Polymer, meets *USP Class VI requirements for plastic containers and closures.*

Polymer Characterization – Polymer is characterized to be composed of an acrylate / peptide mixture that is biologically inert and non-degradable.

Animal Content - This product is manufactured and packaged with animal free materials.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI /AAMI / ISO 11137, "Sterilization of health care products – Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-3} .

Product Attribute – Product designed to promote the growth and attachment of Mesenchymal stem cells.

Quality Control Testing – Representative production samples are collected and inspected in accordance with applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection	-	Pass
Peptide Density	-	Pass
Packaging Inspection	-	Pass

Lot Number Designation:

8 Digit Lot Number: First 3 digits – Julian date, start of manufacturing; Next 2 digits – Year of manufacture; Last 3 digits – Batch identification.

Rev No: 1