Source Chinese:

专利名称　生物型鼻梁植入体

技术领域

本发明的生物型鼻梁植入体涉及一种用于隆鼻手术的医用植入器械，属医学美容整容的植入类（第 III 类）医疗器械。

背景技术

隆鼻是美容整容最常见的手术，目前用于隆鼻的鼻梁植入体全是由硅橡胶或膨体聚四氟乙烯制成，这两种材料虽然具有生物惰性，植入后可与人体和平共处。但由于其组成和结构与人体无任何相似，无法与受主组织长合为一体，易发生移位、磨损，蚀穿外露，细心观察质感仍有差异等缺点。本发明的生物型鼻梁植入体是以动物的肌腱/韧带为原料，经炼制和加工成型，再经环氧固定，多方位除抗原技术及组织诱导技术等系列生化技术处理制成。组成及结构与人体组织相似，生物相容性好，稳定性高，不轻易降解，只有在宿主组织长入时才作被动降解，植入不引起免疫排斥反应，可诱导组织再生，与宿主周围组织长合为一体，并逐渐变为宿主组织。动物实验及临床试验效果良好，是新一代天然鼻梁植入体。

发明内容

本发明提供一种生物型鼻梁植入体的制备方法，这种鼻梁植入体是以动物的肌腱/韧带为原料，塑形定型，交联固定，多方位除抗原，病毒灭活处理，诱导活性修饰，辐射灭菌等步骤制成。制备的具体工艺流程如下：

动物肌腱/韧带→预处理（消毒、修剪为坯料）→脱细胞→成型→交联固定→多方位除抗原→病毒灭活处理→诱导活性修饰→封装→灭菌

这里制备工艺中所说的预处理是指用广谱消毒剂浸泡消毒，去除杂质，并修剪成易于模压成型的坯料。

这里制备工艺中的脱细胞是指用酶解法或去污剂（表面活性剂）洗脱法来脱除肌腱或韧带中的细胞的。酶解法所用的酶有胰蛋白酶和胃蛋白酶。表面活性剂有曲拉通 X100（TritonX100），吐温-20，　乳化剂 OP-10 等。

Target English:

Name of patent Biological model nasal bridge implant

Field of technology

The present invention for a biological model nasal bridge implant involves a medical-use implant device used for nasal bridge reduction surgery; it pertains to the field of plastic surgery implant (class III) medical device.

Technological background

Nasal reduction surgery is the most commonly seen surgery in the field of plastic surgery, and the implants now being used to reduce the bridge of the nose are all composed of silicon or Teflon. Although these two materials are biologically inert and after implantation may coexist peacefully with the human body, because their composition and structure are not at all similar to the human body and they cannot become part of the host tissue, it is easy for them to shift position, abrade, corrode, and for the difference to be detectable through careful observation, among other defects. The present invention for a biological model nasal bridge implant is processed and formed using animal tendons/ligaments as the raw material, refined and processed, and then fixed using epoxy, then multifold antigen removal technology, tissue induction technology and a series of other biochemical technological processes are employed for its manufacture. In composition and construction it is similar to human tissue, with good biocompatibility, high stability, not easily degraded, and only the length of tissue embedded in the host is subject to passive degradation, the implantation does not initiate an immunological rejection response, and it is able to induce the tissue to regenerate and grow into one piece with the tissue around the host, to gradually turn into host tissue. Results are good in animal testing and clinical testing; it is a new generation natural nasal bridge implant.

Nature of the invention

The present invention supplies a preparation method for a biological model nasal bridge implant, this nasal bridge implant is formed using animal tendon/cartilage as the raw material, molding and shaping, crosslinking and fixation, multifold antigen removal, virus deactivation processing, induction of active modification and radiation sterilization and other steps in its manufacture. The specific technical workflow process for preparation is as follows:

Animal tendon/ligament—preprocessing (disinfect, cut into semi-finished material)—cell removal – formation – crosslinking and fixation – multifold antigen removal – virus deactivation processing – induction of active modification—sealed packaging—sterilization

The preprocessing described in this preparation technique means the use of wide-spectrum disinfectants to saturate and disinfect, removal of foreign substances, and trimming into an easily mold-pressed semi-finished material.

Here, the cell removal in this preparation technique means an enzymolysis method or detergent (surfactant) elution method is used to remove cells from the tendon or ligament. The enzymes used in the enzymolysis method are trypsin and pepsin. The surfactants are Triton X100, Tween-20, or emulsifier OP-10.