The research plan

1, and the study background

Protective constraints, also known as physical constraints, the US Bureau of Health care (HCFA) defines it as "with any physical or mechanical equipment, materials or tools attached to or adjacent to the patient's body, so that patients can not easily remove it, in order to limit the free movement of patients or the normal access to their own body". In order to avoid risks such as unplanned extubation and ensure patient safety, the majority of ICU caregivers believe that protective constraint is one of the important measures for the safety management of ICU patients. Therefore, protective constraint has become a common nursing problem in intensive care units at home and abroad. At the same time, with the deepening of humanistic concepts, protective constraints are also getting more and more attention. In 2003, the American Association of Critical Care Medicine developed the clinical implementation guidelines for the technical evaluation of restraint necessity levels, in order to ensure the physical and mental health of ICU patients. In 2004, the British Association of Critical Care Nurses developed practical guidance for adult protective constraints in intensive care units, stating that protective constraints are optimal patient care and should not replace inadequate human resources as one of the routine care measures in the ICU. In 2016, the Nursing Center of the National Institute of Health and Family Planning Hospital Management in China included the "physical constraint rate of hospitalized patients" in the Practical Manual of Nursing Sensitive Quality Indicators, aiming to reduce the overuse of protective constraints in ICU patients.

Constraint equipment refers to the self-injury, may hurt others and patients to limit the activities of the body or a part of the body, in order to achieve the maintenance of the safety of patients, to ensure the smooth treatment, nursing of all kinds of appliances. The essence of the constraint appliance is to limit patient activity to reduce the risk of unexpected adverse events. With the in-depth implementation of quality nursing services, nurses are also paying more

and more attention to restraint nursing, and developed a variety of restraint appliances. Common restraint appliances include bed bars, wrist or ankle restraint belt, restraint vest, shoulder belt or belt type restraint belt, mittens, etc. According to the limitations of traditional restraint appliances, Deng Wandi et al. innovatively made double insurance restraint belt, racket gloves and safety vest. The research results showed that the innovative new restraint appliances can effectively reduce the psychological pressure of nurses and improve the complications caused by restraint. Xu Yan according to the characteristics of severe patients on the basis of the original constraint appliance innovation made safety protection three-piece set of constraint appliance, the appliance consists of safety constraints vest, gloves and knee constraints, the results show that the new constraint appliance can effectively reduce constraints of adverse events, improve family satisfaction.

In view of the above problems, the department developed a new protective restraint device, which is used for the protective restraint of postoperative intubation patients, and summarized nursing experience to provide clinical reference and theoretical basis for standardizing postoperative patient restraint. This project is now a general scientific research project of Zhejiang Provincial Department of Education. The project name is "Research on the Application of New restraint appliance in the Safety Management of Patients after cardiac surgery", and the funding source is

Self-raised.

2, and the study purpose

According to the individual characteristics of ICU patients, combined with the needs of patients, the innovative production of a new restraint appliance and study the effectiveness and safety of the new restraint appliance, to provide clinical reference and theoretical basis for the standardization of postoperative patient restraint.

3. Study design and method:

3.1 This study used random number table to divide the subjects into control and experimental groups.

3.2 The research period of the whole project starts from the date of ethical passage and ends in 2024.

3.3 Inclusion criteria: ① elective surgery patients, age 18; ② preoperative awareness and no communication impairment; ③ open heart surgery under intravenous or inhalation general anesthesia; ④ ICU_During the treatment, endotracheal intubation existed; before ⑤ restraint, there was no joint dysfunction, edema, skin damage, etc. at the proposed restraint site, and the peripheral circulation was good; ⑥ gave informed consent to participate in this study. Exclusion criteria: ① had a history of mental illness; ② had bleeding tendency or skin disease; voluntary abandonment of treatment or death in ③.

3.4 Sampling strategy and grouping: This study used the convenient sampling method to select the research subjects, and then the included subjects were randomly divided into control group and experimental group according to the coin throwing method. The control group used the restraint appliance as the sponge restraint belt, and the experimental group used the restraint appliance as the new restraint appliance.

3.5 Interventions:

3.5.1 Control group: sponge restraint band, restraint method: adjust the fixed wrist band according to the wrist diameter of the patient's hand (foot), and then circle the fixed band around the wristband, one end of the puncture hole without tying, and the two ends of the fixed band are fixed on both sides of the bed as needed.

3.5.2 Experimental group: new restraint appliance, which is an adjustable protective restraint device (patent No. ZL202020155913.1), including upper bracket 1, upper bracket 2, lower bracket 2 and gloves; the multiple fixed supports are provided with air holes and breathable cotton to increase air permeability and comfort. Place the patient's elbow with the lower fixed bracket one and two, and then connect the upper fixed bracket one and the upper and lower fixed bracket two, and adjust the tightness, and the other to form a removable and rotating connection in a certain angle range to adjust the movement angle of the patient's elbow joint; set the patient's hand with the palm of the glove. The device was commissioned by Anshan Deyi Da Medical Device Technology Co., LTD.

(Business license registration number: 912103003966197061, class I medical device production record No.: Liaoan Food and Drug Device Production Preparation 20200011).

3.6, Outcome measures

.13.6 Outcome decision time

This study starts with the use of the protective restraint tool after surgery until the removal of the endotracheal tube..23.6 Main outcome measures

I Adverse event rate of nursing care:

Unplanned extubation rate: unplanned extubation includes a self-extubation without the consent of medical staff; b. Pipeline slip caused by various reasons; c. Extubation needs to be performed in advance due to catheter quality problems and catheter blockage. Unplanned extubation rate = number of unplanned extubation cases in the same period / total number of ICU inpatients in the statistical period 100%.

.73 Data collection

Data were collected by on-site assessment and medical record review. General demographic data including age, gender, education, marital status, occupation, smoking, alcohol consumption, health insurance type, surgical mode, admission diagnosis, history of underlying diseases, were collected by the investigator by medical record review. The incidence of nursing adverse events, duration of restraint period, cumulative dose of sedation used, length of ICU stay, and total cost of ICU treatment were collected by the investigator through the electronic medical system and integrated nursing information platform before pre-transfer to the ICU. Anxiety, depression and comfort were assessed by the responsible nurse within 24h after the patient woke from anesthesia and on the day the patient was pre-transferred out of the ICU.

.83 Quality control

.8.13 The hospital has established a unified and standardized restraint process, and will regularly regular restraint and skin care training for nurses.

.23.8 Each class has a responsible leader, who will check the skin assessment and the rigor of nursing records, and ensure the quality of nursing records.

3.8.3 Double verification during data collection and entry.

.93 Statistical analysis

.0 Statistical analysis by SPSS 25 software, frequency and percentage for count data, chi-square test or Fisher test for between-group comparison, mean ± standard deviation for normal distribution data, t-test for groups, non-normal distribution data, and non-parametric test for between-group comparison. A $P < 0.05$ was considered as a statistically significant difference.

4.1 The subjects analyzed in this study are all vulnerable groups after cardiac surgery. For subjects, the data obtained in this study are only used for research, and they are not publicly available outside the scope permitted by relevant laws and / or regulations.

4, and the sample size calculation

The test group and the control group were selected separately 5 For example, patients.

5, and data management and confidentiality

All records concerning the identity of the subject are kept confidential and are not publicly available beyond the extent permitted by the relevant laws and / or regulations.

6, and gave an informed consent

For the patients who meet the inclusion criteria, the physician in charge will inform the patients and their families of the purpose of the protective restraint and the related risks that may occur.

7, and the reporting of the adverse events

Take corresponding measures in time, and record them in the case report form.

8, Product introduction

The control group used the sponge restraint belt full name: medical care mat, the specification and model are: limb restraint belt (limb belt type). Manufacturer: Zhejiang Province, Zhuji City, Shaoxing City, Chengnan Shuda medical supplies factory.

The experimental group used an adjustable protective restraint device, including upper bracket 1, upper bracket 2, lower bracket 1, lower bracket 2 and gloves; air holes and breathable cotton to increase air permeability and comfort. Place the patient's elbow with the lower fixed bracket one and two, and then connect the upper fixed bracket one and the upper and lower fixed bracket two and adjust the tightness, and the other to form a removable and rotating connection in a certain angle range to adjust the movement angle of the patient's elbow joint; set the patient's hand with the palm of the glove.

The national standards of the product comply with GB / T 16886.10-2017 / ISO 10993-10:2010 criteria for biological evaluation of medical devices-Part 10: Test for irritation and skin sensitization. Product-related qualifications and physical objects are shown in the following figure.

Fig. 1. Production qualification

第一类医疗器械备案凭证

鞍山德益达医疗器械科技有限公司：

根据相关法规要求，对你单位第一类医疗器械：肢部固定器予以备案。备案号：辽鞍械备 20200023 号。

鞍山市行政审批局
（盖章）
日期：2020 年 4 月 17 日

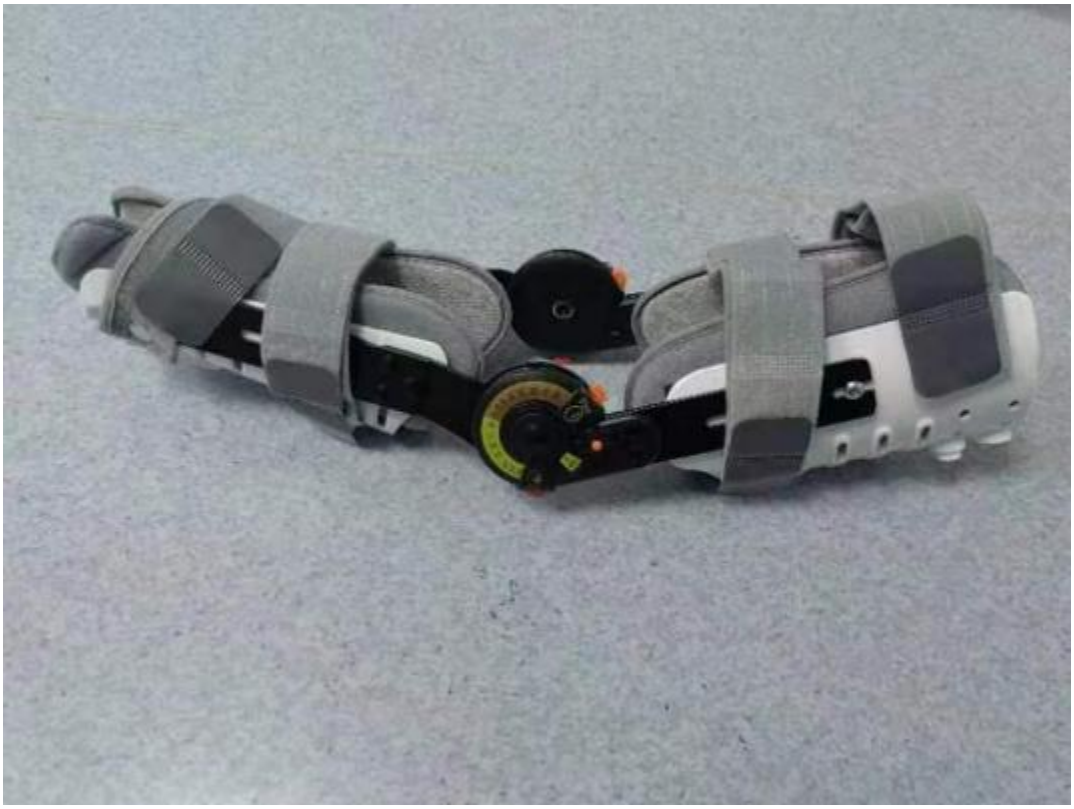
第一类医疗器械生产备案凭证

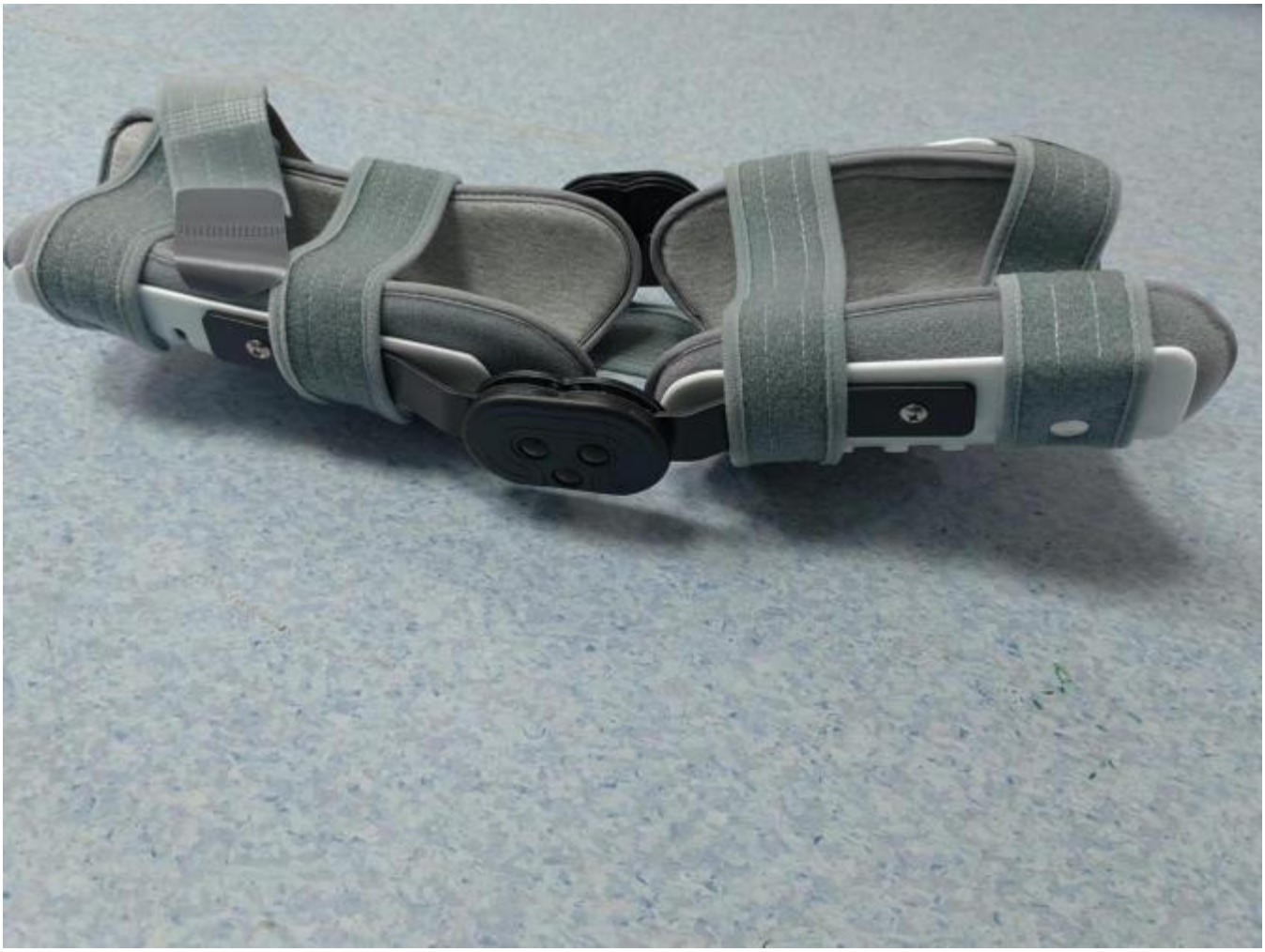
备案编号：辽鞍食药监械生产备 20200011 号

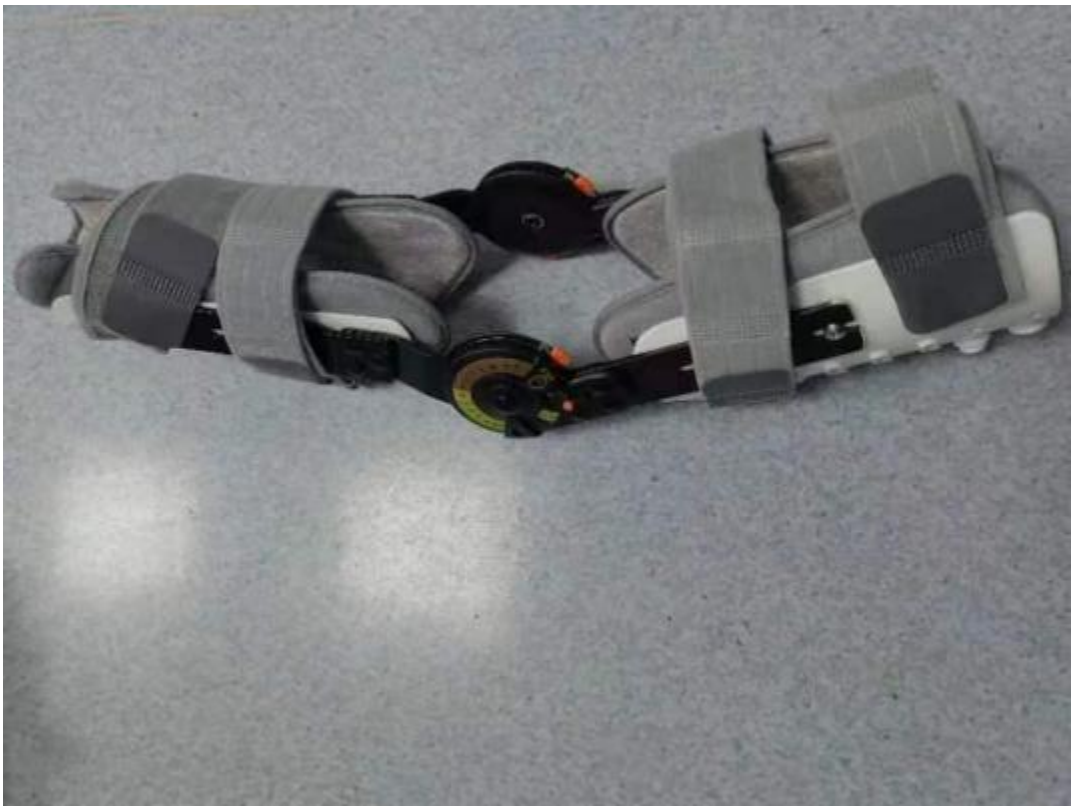
企业名称	鞍山德益达医疗器械科技有限公司			
住　所	辽宁省鞍山市高新区越岭路 263 号（北园 4 号楼北座 3 楼）			
生产地址	辽宁省鞍山市高新区越岭路 263 号（北园 4 号楼北座 3 楼）			
法定代表人	王申义	企业负责人	王申义	
生产范围	2002 分类目录 I 类：6810-13-矫形外科（骨科）用其他器械；6864-1-医护用品 2017 分类目录 I 类：13-14-医护人员防护用品；13-04-矫形固定器械			
生产产品列表	产品名称	产品备案号	登载日期	备注
	医用隔离衣罩	辽鞍械备 20200007 号	2020-02-24	
	肩部固定器	辽鞍械备 20200013 号	2020-04-13	
	腰部固定器	辽鞍械备 20200014 号	2020-04-13	
	颈部固定器	辽鞍械备 20200015 号	2020-04-13	
	腋部固定器	辽鞍械备 20200016 号	2020-04-13	
	足部固定器	辽鞍械备 20200017 号	2020-04-13	
	踝部固定器	辽鞍械备 20200020 号	2020-04-13	
	胸部固定器	辽鞍械备 20200021 号	2020-04-13	
	腕关节固定器	辽鞍械备 20200022 号	2020-04-13	
	肘部固定器	辽鞍械备 20200023 号	2020-04-13	
	医用隔离眼罩	辽鞍械备 20200024 号	2020-04-13	
	医用帽	辽鞍械备 20200027 号	2020-05-18	
	隔离衣	辽鞍械备 20200028 号	2020-05-18	
	医用隔离鞋套	辽鞍械备 20200029 号	2020-05-18	

备案部门（公章）辽宁省鞍山市行政审批局
备案日期：2020 年 5 月 18 日

Fig. 1. Production qualification







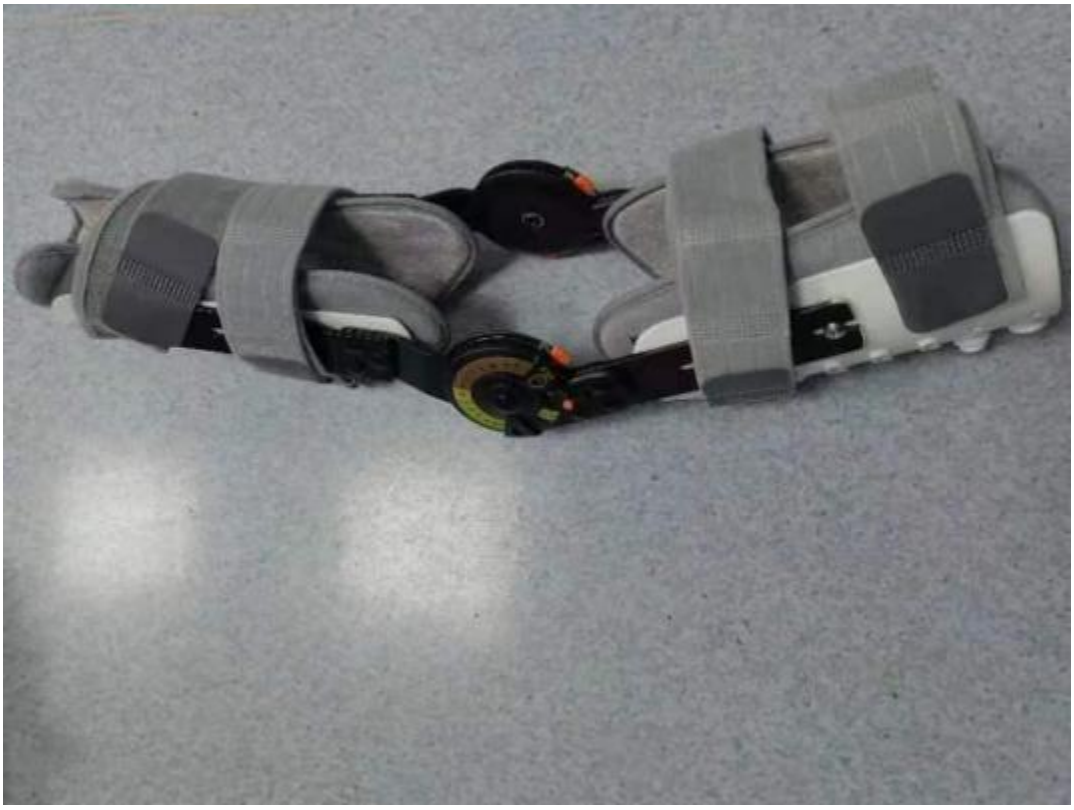


Figure 2 Physical picture