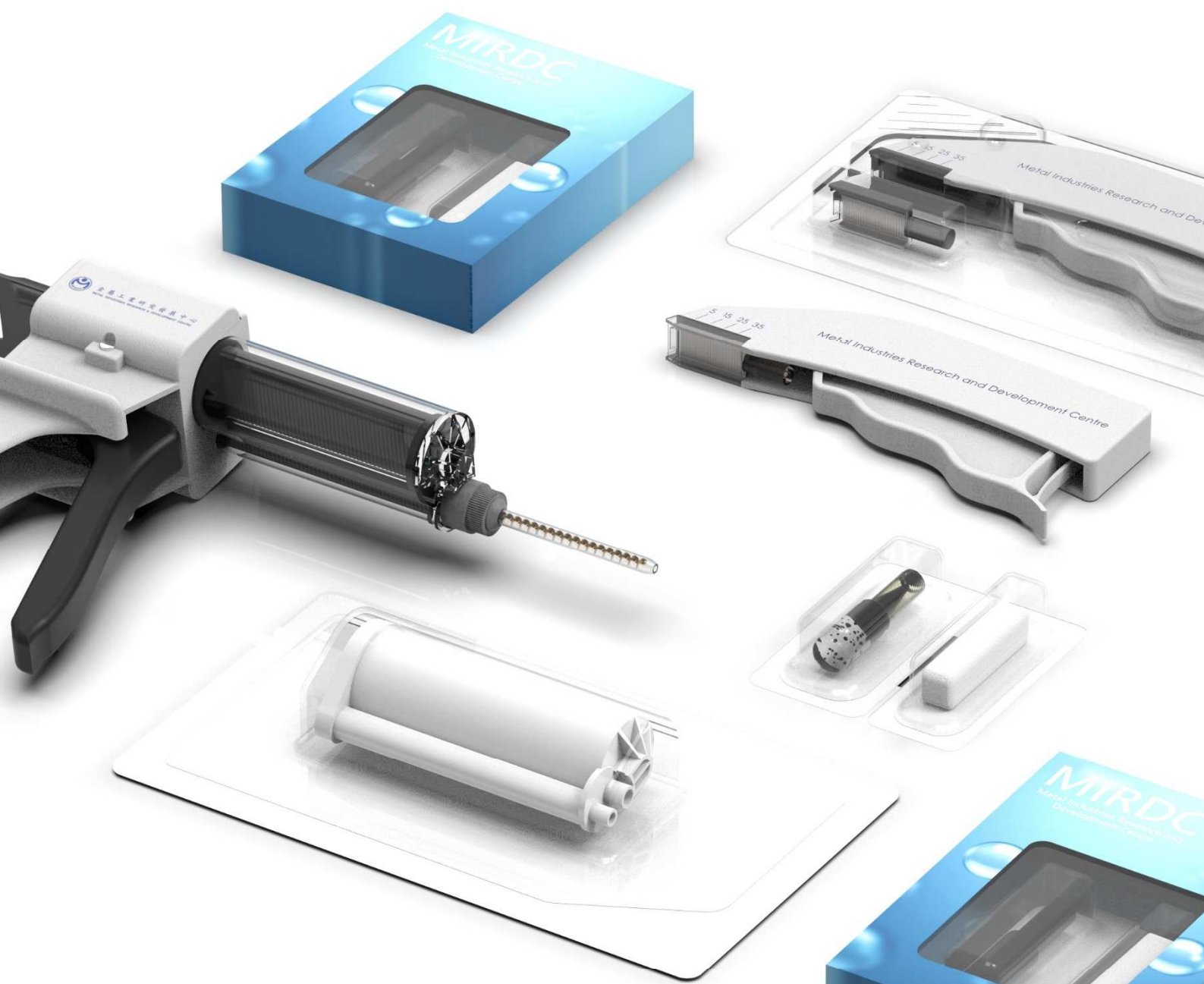


Materials for Bone Defect Repair

修復骨缺損用填補系統

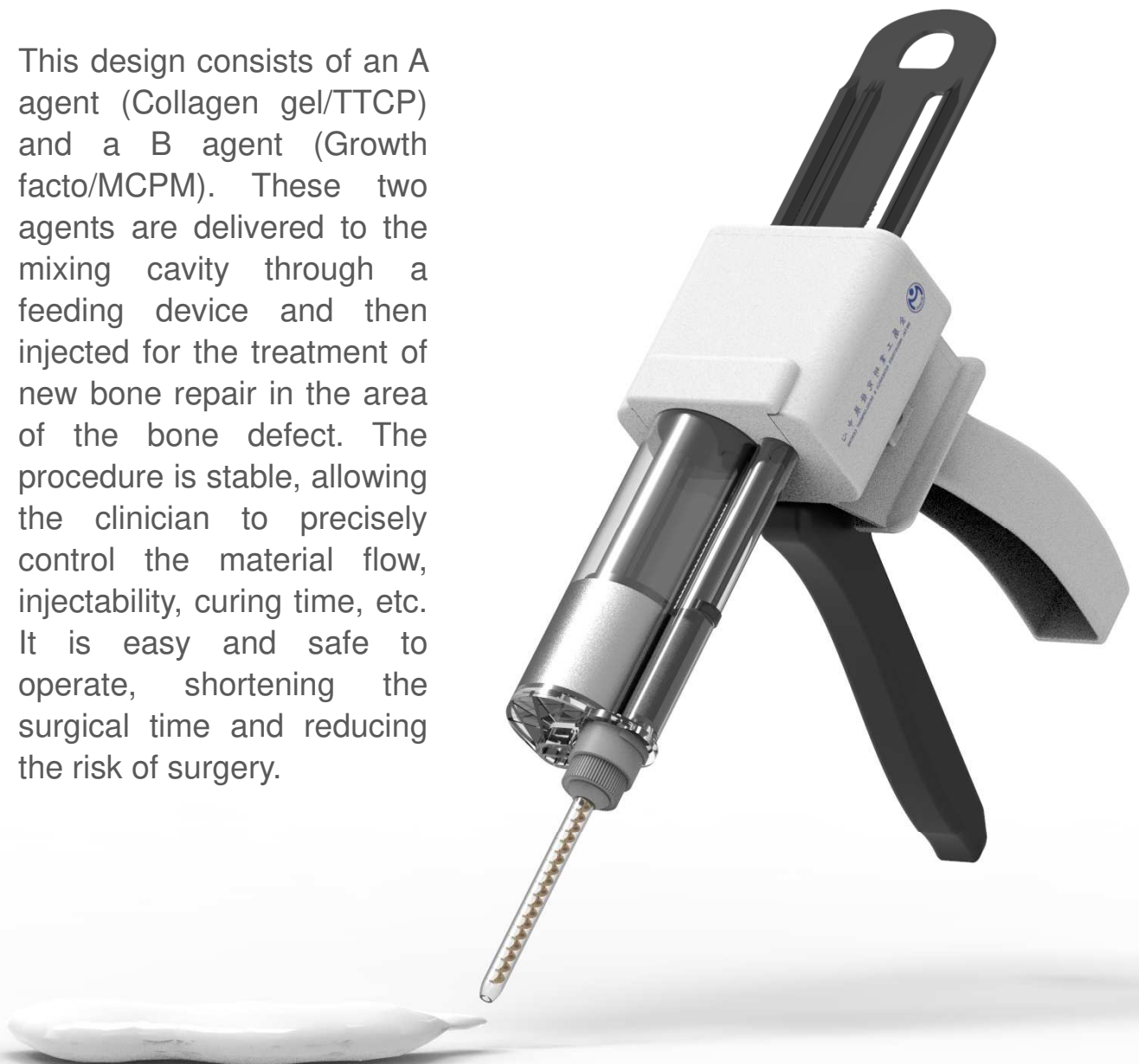


Metal Industries Research and Development Centre
Combination Medical Device Technology Division , Medical Devices R&D
Service Department

Diversified bone filling material, to meet clinical needs.

Traditionally, bone block implants, bone cement, and allogeneic bone are used to treat bone defects, but clinical results have been mixed. The anesthesia time is prolonged because of the tedious process of cutting the bone filling material during the surgery, and new tissues do not easily grow into the bone defect area, which results in a re-fracture rate of 25% after 18 months of the surgery. The growing elderly population and sports injuries are the main reasons for the increase in the prevalence of bone defects. Since multiple bone defects cannot be regenerated, there is a pressing need in the market for advanced bone regeneration materials and easy surgical procedures.

This design consists of an A agent (Collagen gel/TTCP) and a B agent (Growth facto/MCPM). These two agents are delivered to the mixing cavity through a feeding device and then injected for the treatment of new bone repair in the area of the bone defect. The procedure is stable, allowing the clinician to precisely control the material flow, injectability, curing time, etc. It is easy and safe to operate, shortening the surgical time and reducing the risk of surgery.



Simplify surgical procedure - Shorten the surgery time for bone defect repair.

The use of conventional standardized bone fillers for clinical surgery of large bone defect repair is time-consuming and increases the complexity of the surgery, which can easily lead to medical risks. This design is a moldable bone filling material that can be used for minimally invasive surgery and complex structural bone defects to promote bone cell and blood vessel growth. Collagen gel/TTCP/MCPM/ and growth factor materials are mixed in the cavity and then combined with innovative instruments to fill the bone defect directly. It can be used clinically for all types of bone defects, eliminating the tedious surgical procedures and the psychological stress of the medical staff. Surgical procedures can be shortened and risks reduced during the COVID-19 epidemic, making them easier and safer to perform.



Simple design, Simplify surgical procedure , Convenient for clinical use.

This design meets the clinical needs of bone defect repair with two types of filling methods: a two-syringe mixing pump and flexible hydration-curing bone regeneration material. The two-syringe mixing pump is delivered to the injection chamber through a feeding device for homogeneous mixing and injecting to achieve a new bone filling and curing process in the bone defect area. The other system is flexible hydration-curing bone regeneration material, which is mixed with a liquid softening agent and then rubbed to soften the bone filling material to shape it, and can be filled into large bone defect areas. The two methods can be used in conjunction with each other or independently as needed in clinical practice. It is easy to operate, which is beneficial for physicians to operate independently and reduce the risk during surgery.



Appropriate Aesthetics

Currently, the "Materials for bone defect repair" has been launched in the market and cooperated with medical equipment manufacturers and medical institutions, which not only accelerates the development of the application of biomaterial industry but also provides new choices in treatment.

The design is ergonomic, easy to hold and operate with one hand, easy to grip, slip-proof, simple, fast, smooth, safe, etc., reflecting the beauty of simplicity and achieving the effect of safety and instant. The design is in accordance with ISO10993 test specification and has passed the biological toxicity, irritation, and allergy test. It has also applied for IRB test to confirm that it can control its degradation rate and complete absorption, which is safe and reduces post-operative risks and disputes.

The product has been recognized with several international awards, including the Red Dot Design Award in Germany, the MUSE Design Award in USA, and The R&D 100 Awards.



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Benefit to User

It is difficult to anastomose the defect area with a traditional bone block, and the material is brittle and easy to break when filling, and the degradation rate of the traditional bone block is too slow, thus limiting the growth of bone tissue.

The bone filler is designed with a biomimetic composite material, combining natural high polymer porosity with calcium phosphate hydration curing technology. The design is flexible and suitable for a wide range of bone defect indications, increasing surgical flexibility and creating new value together with innovative instrumentation. It can meet clinical needs for initial hardening after injection to achieve temporary strengthening and fixation, be easy to combine with complex-shaped bone defects, repair, and the porous nature of the material can provide blood nutrient transfer, solving the current problems of bone reconstruction clinical operation and the dilemma of bone tissue regeneration. As a result, bone reconstruction can effectively restore the basic function of bone, reduce follow-up medical disputes, and ameliorate the current situation of traditional surgery.

Reduce packaging pollution and energy consumption, energy saving and carbon emission reduction.

The system is designed with non-disposable consumable materials and can be used by patients after sterilization, achieving environmental protection and carbon emission reduction. The simple design of the kit and the case makes them simple to use and allows the surgeon to perform the surgery independently with no assistance from others, reducing the risk during the surgery.

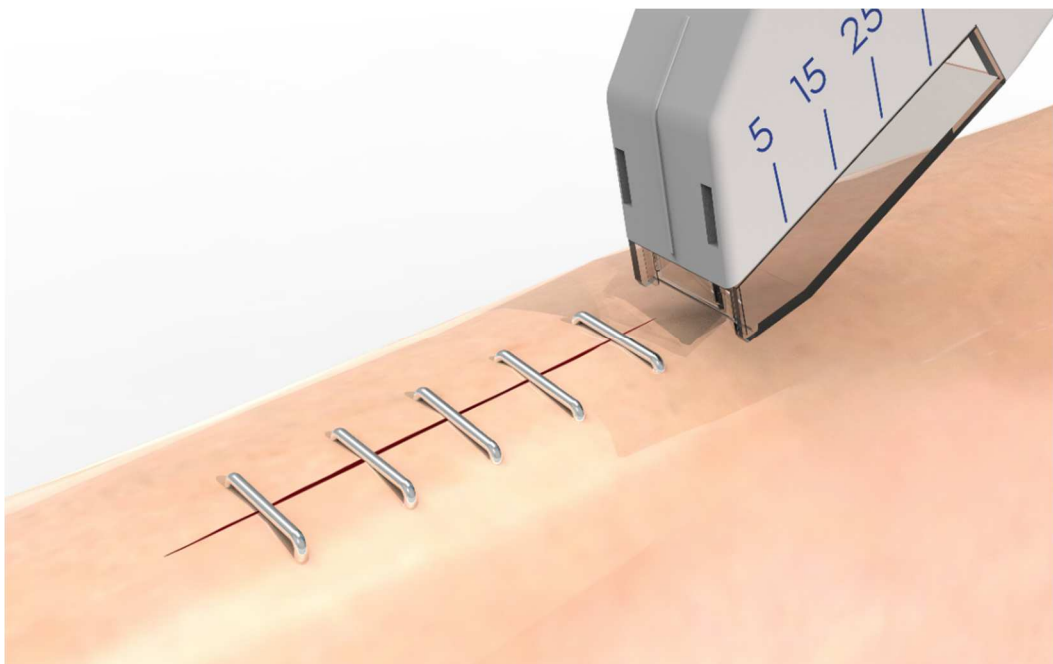
The product has been promoted by clinical physicians and orthopedic researchers and has received the support and approval of many physicians. Currently, the clinical use data feedback is growing, and the inspection, registration, and related data for the pre-launch preparation of medical materials has been conducted.



Safe, Simple, Fast, Convenient and Low Risk.

The growing elderly population and sports injuries are the main reasons for the increase in the prevalence of bone defects. Since multiple bone defects cannot be regenerated, there is a pressing need in the market for advanced bone regeneration materials and easy surgical procedures.

Conventional surgical sutures cause post-operative aesthetic problems due to suture compression and anastomosis of the wound. The design allows the magnesium alloy staples to fit and stabilize the wound, reducing the distortion of the wound. It can prevent the formation of centipede-like scars or keloid swelling after surgery, prevent pain and itchiness caused by scars, and eliminate the need for scar reduction injections and laser scar removal surgery. The degradable and absorbable characteristics of the magnesium alloy staples allow for painless degradation and staple removal, shortening the wound healing time for patients and the inconvenience of returning to the clinic for the removal of stitches.



Patent

The " Materials for bone defect repair " is safe and reliable for medical treatment, minimizing the concerns of osteoporosis patients during surgery, and has great potential in the international medical market. The " Materials for bone defect repair " is highly compatible with existing tools and, in the future, can be applied for different medical indications for use, and flexible modes of combination can be derived to create unprecedented possibilities and contribute to the well-being of human life. The simple design of the kit and the case makes them simple to use and allows the surgeon to perform the surgery independently with no assistance from others, reducing the risk during the surgery.

The product has been promoted by clinical physicians and orthopedic researchers and has received the support and approval of many physicians. Currently, the clinical use data feedback is growing, and the inspection, registration, and related data for the pre-launch preparation of medical materials has been conducted.

The design has been patented in Taiwan (I504375), (I589278), China (CN106725927B), Japan (特許第 JP6300876B2 号), the United States (US9,700,397B2), and Germany (DE102016118584.A1). The patent is a guarantee for the marketing and sales of medical devices.





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