

Screw

Instructions for use

01 Intended use

A sterile, single-use medical device consisting of a screw that stabilizes bone by fixing and tightening bone tissue to a plate.

02 Preparation before use

1. Check that the product packaging is not damaged.
2. Check for missing product components.
3. The product is supplied sterile. Check the packaging for damage and use only sterile products.
4. The physician must fully understand the surgical technique using these instruments, clinical indications and contraindications.
5. Confirm that no biological or biomechanical factors may compromise the surgical outcome.
6. Read and understand the instructions before use.

03 Operation

1. Determine the exact location of the surgical site and the plate size.
2. Prepare a bone fixation screw of the size appropriate for the surgical site.
3. Bend the bone fixation plate to fit the surgical site.
4. Position the plate at the surgical site and drill a hole. Use a drill dimension smaller than the hole in the plate.
5. Insert the bone fixation screw into the hole in the plate.
6. Tighten the screw with a screwdriver, firmly joining the plate and fracture site using the screw.

04 After-use care

This is a sterile, single-use medical device. Never reuse. Reuse is prohibited.

05 Storage

1. Store at room temperature, 1-30°C.
2. Store away from direct sunlight.

06 Sterilization

Ethylene oxide (EO) gas sterilization

07 Precautions

1. For use only by physicians or medical specialists. Use outside the intended purpose is prohibited.
2. Understand the product instructions before use.
3. Maintain sterility at every stage of handling the instruments.
4. Do not reuse a used product. Use a new product if damage or deformation is present.
5. Select the appropriate size, shape and position for use.
6. Do not deform the product by applying force. If the practitioner judges modification necessary, take care not to damage the product.
7. Do not use the product if body fluids get on it during the procedure. Pathogenic infection from body fluids may occur.
8. Detachment may occur over time after attachment. Removal from the treatment site must be judged and performed according to the patient's condition.
9. Take special care in pediatric patients. Use in children may cause growth restriction.
10. Do not use for purposes other than those stated in the instructions.
11. Do not use when any of the contraindications below apply.

08 Do not use in the following cases

Active or potential infection

Severely comminuted bone

Insufficient blood supply

Treatment of maxillofacial fractures

Osteosynthesis in the load-bearing region of the maxillofacial skull