

스크류 사용설명서

특수재질골절합용나사 · 제조사 Rev.1 · 영문

수록 자료

제조사 P&S Manual (Rev.1) 중 Screw Manual · 영문 1쪽
동일 내용이 좌우에 반복 배치된 원본 인쇄 양식을 유지했습니다.

포함 내용

사용 전 준비사항, 조작방법, 사용 후 관리, 사용 시 주의사항,
보관과 멸균방법

열람 안내

보관된 Rev.1 원문이며 최신 개정본임을 보증하는 표시는 아닙니다.
실제 사용 전 제품의 모델·표시사항과 동봉된 최신 설명서를 확인하세요.
제품별 최신 국문 설명서와 사용기한은 글로원에 문의해 주세요.

[Orthopedic Biodegradable Bone Screw Manual]

[Performance and Purpose of use]

- This Product is a disposable medical device sterilized with a Screw that provides stability to the bone by fixing and tightening the one tissue on the plate.

[Preparation before use]

1. Check whether the packaging of the product is damaged.
2. Check for any missing parts of the product.
3. Since this product is supplied in a sterilized state, use the product after checking whether the packaging material is damaged.
4. The operator must fully know the surgical method using this product, clinical indications and contraindications.
5. Confirm that there are no biological or biomechanical factors that may hinder the surgical outcome.
6. The operator must carefully read the instruction manual before using

[How to use]

1. Determine the exact location of the surgical site and the size of the plate.
2. Prepare a orthopedic biodegradable bone screw of the size suitable for the surgical site.
3. Make a shape by bending the orthopedic biodegradable bone plate according to the surgical site.
4. Place the orthopedic biodegradable bone plate on the sugical site and make the hole with a drill.
(At this time, the drill uses a smaller dimension than the hole in the plate.)
5. Insert the orthopedic biodegradable bone screw into the hole of the orthopedic biodegradable bone plate.
6. Tighten the orthopedic biodegradable bone screw with a screwdirver.
 - Using the orthopedic biodegradable bone screws, the orthopedic biodegradable bone plate and the fracture area are firmly joined.

[Storage and management method after use]

1. This product is a sterilized disposable medical device product, so it must not be reused. (Reuse prohibited).

[Precaution for use]

1. This product cannot be used by anyone other than doctors or specialists, and use for other purposes is prohibited.
2. Read the contents of the product manual before use.
3. Always keep sterile at all stages of handling equipment.
4. Prohibit reuse and use new products if there is damage or deformation.
5. Select appropriate size, shape, and location to use this product.
6. Do not cause deformation by applying force to this product. If modification of this product is required according to the judgment of the practitioner, be careful not to damage the product.
7. If body fluids get on this product during the procedure, it should not be used. Pathogenic infections from body fluids can occur.
8. After attaching this product, it may be detached over time. When the attached product is removed from the treatment site, it is judged and executed according to the patient's condition.
9. Pediatric patients should be treated with special care. When used in pediatric patients, this product may cause growth restrictions.
10. Do not use for any other purpose other than those indicated in the instructions.
11. Do not use in the following cases.
 - If there is an active and potential infection
 - Seriously crushed bones
 - Insufficient blood supply
 - When dealing with maxillofacial fractures
 - In case of bone splicing to the load-bearing area of the skull of the maxillary

[Storage method]

1. Store at room temperature (1~30°C).
2. Store in a place out of direct sunlight.

[Sterilization method] EO gas

[Manufacturer]

GLOONE Co., Ltd. (30001) 228-9, Sojeonggu-gil, Sojeong-ri, Sojeong-myeon, Sejong-si, Republic of Korea

[Orthopedic Biodegradable Bone Screw Manual]

[Performance and Purpose of use]

- This Product is a disposable medical device sterilized with a Screw that provides stability to the bone by fixing and tightening the one tissue on the plate.

[Preparation before use]

1. Check whether the packaging of the product is damaged.
2. Check for any missing parts of the product.
3. Since this product is supplied in a sterilized state, use the product after checking whether the packaging material is damaged.
4. The operator must fully know the surgical method using this product, clinical indications and contraindications.
5. Confirm that there are no biological or biomechanical factors that may hinder the surgical outcome.
6. The operator must carefully read the instruction manual before using

[How to use]

1. Determine the exact location of the surgical site and the size of the plate.
2. Prepare a orthopedic biodegradable bone screw of the size suitable for the surgical site.
3. Make a shape by bending the orthopedic biodegradable bone plate according to the surgical site.
4. Place the orthopedic biodegradable bone plate on the sugical site and make the hole with a drill.
(At this time, the drill uses a smaller dimension than the hole in the plate.)
5. Insert the orthopedic biodegradable bone screw into the hole of the orthopedic biodegradable bone plate.
6. Tighten the orthopedic biodegradable bone screw with a screwdirver.
 - Using the orthopedic biodegradable bone screws, the orthopedic biodegradable bone plate and the fracture area are firmly joined.

[Storage and management method after use]

1. This product is a sterilized disposable medical device product, so it must not be reused. (Reuse prohibited).

[Precaution for use]

1. This product cannot be used by anyone other than doctors or specialists, and use for other purposes is prohibited.
2. Read the contents of the product manual before use.
3. Always keep sterile at all stages of handling equipment.
4. Prohibit reuse and use new products if there is damage or deformation.
5. Select appropriate size, shape, and location to use this product.
6. Do not cause deformation by applying force to this product. If modification of this product is required according to the judgment of the practitioner, be careful not to damage the product.
7. If body fluids get on this product during the procedure, it should not be used. Pathogenic infections from body fluids can occur.
8. After attaching this product, it may be detached over time. When the attached product is removed from the treatment site, it is judged and executed according to the patient's condition.
9. Pediatric patients should be treated with special care. When used in pediatric patients, this product may cause growth restrictions.
10. Do not use for any other purpose other than those indicated in the instructions.
11. Do not use in the following cases.
 - If there is an active and potential infection
 - Seriously crushed bones
 - Insufficient blood supply
 - When dealing with maxillofacial fractures
 - In case of bone splicing to the load-bearing area of the skull of the maxillary

[Storage method]

1. Store at room temperature (1~30°C).
2. Store in a place out of direct sunlight.

[Sterilization method] EO gas

[Manufacturer]

GLOONE Co., Ltd. (30001) 228-9, Sojeonggu-gil, Sojeong-ri, Sojeong-myeon, Sejong-si, Republic of Korea