

INSTRUCTIONS FOR USE

Sterile Single Use Instruments

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CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician

DESCRIPTION

The Sterile Single-Use Instruments/Kits contain various instruments to aid in bone preparation and implant insertion. These instruments include but are not limited to: Insertion instruments, Sizing instruments, Reamers and K-wires

MATERIALS

The patient contacting materials of the instruments contained in these kits may contain the materials listed below. Not all materials are present in every kit. Materials are listed on the product labeling.

Stainless Steel
Polycarbonate
Nylon

WARNINGS

1. The surgeon is to be familiar with the equipment, instruments and surgical procedure prior to performing surgery
2. These instruments/kits are single use only. After use, the instruments may be potential biohazards. Reuse of instruments labeled for single-use may result in product contamination, patient infections and/or failure of the instrument to perform as intended.
3. Do not use instruments that have been, even momentarily, placed in a different patient.
4. Do not use if there is a loss of sterility of the instrument.
5. Discard and DO NOT USE opened or damaged instruments, and use only instruments that are packaged in unopened or undamaged containers.
6. Correct handling of instruments is extremely important. Instruments are not intended to be modified, notched, bent etc. as notches, scratches or other damage and/or wear in the instrument occurring during surgery may affect the performance of the instrument or contribute to breakage. Note: Certain instruments are intended to remain pliable during use. However, repeated bending and extensive use may decrease effectiveness of the devices.

PRECAUTIONS

- The cannulated reamers are designed for use with the supplied k-wires.
- Surgical instruments are subject to wear with usage.
- Instruments that have experienced extensive use or excessive force are subject to fracture.
- Surgical instruments should only be used for their intended purpose.
- All instruments and packaging must be removed prior to closing the surgical site. Do not implant.
- The patient is to be warned by his/her physician of all surgical risks.

STERILITY






Sterile Single Use Instruments are sterilized by exposure to a minimum dose of 25kGY of gamma irradiation. Individual product labels identify the type of sterilization. Do not resterilize. Do not use devices after expiration date has passed.





STORAGE CONDITIONS

Products must be stored in a clean, dry environment.

The Surgical Technique Manual is available on the Bio2 Technologies website (www.bio2tech.com) or may be obtained by calling the company +1.781.569.0559

Definitions of symbols and abbreviations.

| Symbol | Definition |
|---|---|
|  | Lot Number (Batch Code) |
|  | Catalog Number |
|  | Do not re-use |
| Rx Only | For prescription use only |
|  | Caution, consult accompanying documents |
|  | Consult operating instructions |

| Symbol | Definition |
|--|---|
|  | Use by |
|  | Manufacturer |
| STERILE R | Sterilized using irradiation |
| SS | Stainless Steel |
|  | Not to be used in case package is damaged |
|  | Do not resterilize |