



## SURGICAL INSTRUMENT – CARE AND HANDLING INSTRUCTIONS

Supplied Sterile – Single Use Only

Carefully read all instructions and be familiar with the surgical techniques prior to use.

### DEFINITION OF SYMBOLS



Medical device



Use by



Method of Sterilisation; Gamma Irradiation



Non-Sterile



Caution



Read usage instructions



Not to be used if package is damaged



Do not resterilise



Single use



Catalogue number



Manufacturer



Date of manufacture



Double sterile barrier system



Lot number



Authorised representative in the European Community



Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

### DESCRIPTION

C-Pin™ surgical instruments are designed to perform specific functions such as pinning, cutting and drilling.

C-Pin™ surgical instruments may also be used to facilitate the insertion of surgical implants.

### MATERIALS

C-Pin™ surgical instruments are manufactured from stainless steel.

### INSPECTION

Inspect for damage to package or seal before opening. Sterility is only guaranteed if package is undamaged or unopened.

Carefully inspect instrument for damage. Damaged or defective instruments should not be used. If damaged, do not use and contact the manufacturer's customer service or your local sales representative for a replacement.

### WARNINGS

1. Do not reuse surgical instruments labeled for single use only. Reuse could adversely affect performance of the instrument.
2. Do not use cutting tools that are deformed, corroded, damaged or worn. For safe use, instrument must be free of broken or dull cutting edges.
3. Do not subject instruments to excessive force and / or impact as breakage can occur.
4. Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application.
5. Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid distal migration and possible injury.

6. Delicate structures close to operation site must be protected.
7. Firm control of the instrument must be maintained to avoid injury to patient or operating room personnel.
8. Should the tip section of the instrument come into contact with other metallic objects it may cause instantaneous damage and destructive failure of the device.

### PRECAUTIONS

1. Use aseptic technique to open package for delivery of device into sterile field.
2. Medical devices require special handling to prevent damage. As with all medical devices, careful attention should be made to assure that excessive force is not placed on the instrument. Excessive force may result in instrument failure.
3. Surgeons must be skilled in the use of cutting tool surgical instruments.
4. The use of an instrument in any manner or medical procedure other than those for which it is designed and indicated may result in damage or breakage.
5. Drill bit breakage most often occurs when working around metallic implants (prosthetic components, internal fixation devices, etc.). To minimise these incidents, ensure that the tip of the drill bit does not contact an implant. In case of breakage and presence of drill bit fragments, follow the appropriate orthopaedic surgery protocol.

### LIMITED WARRANTY

The product is guaranteed for materials, function and workmanship for patient use. The manufacturer shall not be liable, expressly or implied, for any damages which might arise or be caused, whether by the customer or by any of the users of the product, as a result of:

1. Misuse, mishandling, and / or improper operation.
2. Use in any manner or medical procedure other than those for which it is designed.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND / OR STATUTORY, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS, AND / OR LIABILITIES ON APEX'S PART.

### PRODUCT COMPLAINTS

All questions or concerns related to quality, reliability and / or durability of this product should be directed to manufacturer customer service or an authorised representative of the manufacturer. Please contact customer service or an authorised representative for a return authorisation.

### SUPPLIED

Supplied sterile. Sterility is guaranteed unless the package is damaged or open. For professional use only.

### STORAGE

Store in enclosed dust free environment away from direct sunlight below 30°C (86 °F). Maintain a relative humidity range of between 20% — 80%.



#### Manufacturer

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