

General Instrumentation Instructions for Use

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Description

The following instructions are for general surgical instruments provided by Trilliant Surgical. Such instruments include, but are not limited to, drill bits, countersinks, reamers, depth gauges, bone clamps, distraction pliers, bending instruments, drill guides, screw removal tools and drivers.

Instrument Materials

All instrumentation is made from medical grades of stainless steel and anodized aluminum.

Indications

Trilliant instruments are designed to perform a specific function, such as cutting, broaching, measuring, reaming, grasping, clamping, dissecting, probing, inserting, impacting, positioning/removing, retracting, fixating, and drilling. Instruments are for use by, or as directed by, a physician or surgeon. Instruments should only be used for the purpose for which they were designed. The proper technique for the use of the instrument is the sole responsibility of the medical professional.

Contraindications

Use of Trilliant instruments is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; or in patients with certain metabolic diseases.

Warnings

1. Instruments are to be treated as sharps.
2. Re-use of instruments indicated as single use can result in decreased mechanical and clinical performance.

Maintaining Device Effectiveness

1. The user should have specific training, experience, and thorough familiarity with the use of the required instrumentation.
2. The user must exercise reasonable judgment when deciding which instrument to use for specific indications.
3. Failure to use dedicated, unique Trilliant Surgical instruments for every step of the surgical technique may compromise the integrity of the instrument or implanted device, potentially leading to patient injury.
4. Carefully inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments that are faulty, damaged, worn or suspect should not be used.
5. Trilliant Surgical recommends the use of Trilliant Surgical products in a sterile environment.

Cleaning

Non-sterile products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents. For validated cleaning instructions, please reference document 900-06-017, General Instrumentation Cleaning and Sterilization Protocol.

Packaging and Sterility

NON-STERILE PRODUCT

Trilliant Surgical instruments will be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed.

| Sterilization Method | Pre-Vacuum Steam | Gravity Steam |
|----------------------|----------------------------|----------------------------|
| Condition | Condition: Wrapped* | Condition: Wrapped* |
| Temperature | Temperature: 270°F (132°C) | Temperature: 270°F (132°C) |
| Time | Time: 4 minutes | Time: 40 minutes |
| Dry Time | Recommended 60 minutes** | Recommended 70 minutes** |

* The system shall be packaged for sterilization by double wrapping in standard central supply wrap (i.e. Bio-Shield® Sterilization Wrap).

** Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.













CAUTION

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

Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments or implants.

Inspect all components preoperatively to assure utility.

Symbol Definitions

 Batch Code  Catalogue Number  Quantity  Do not use if package is damaged  Do not re-use  Device has no expiration  Non-Sterile
 Device only to be sold on or by the order of a physician  Manufacturer  Date of Manufacture  Caution  Consult Instructions for Use


Trilliant Surgical LTD
727 North Shepherd Drive, Suite 100
Houston, TX 77007
1-800-495-2919

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.