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.

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

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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	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	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.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2016
REF	Catalog Number	5.1.5
LOT	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
NON STERILE	Non-Sterile	5.2.7
Rx only	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements. Note: QTY is an abbreviation of "QUANTITY".

Trilliant Surgical
727 North Shepherd Drive | Suite 100 | Houston, TX 77007
1-800-495-2919 | trilliantsurgical.com