X-Twist Reusable Instrumentation

Important Product Information

Instructions for Use

31923 Rev 1 ANIKA Eff. 07/22
www.anika.com
(941)755-7965
Mfd by:
Parcus Medical, LLC
6423 Parkland Dr.
Sarasota, FL 34243

1. **Indications:**

    A. Anika offers a variety of reusable instrumentation intended for use in the surgical environment. This includes various types of inserters, taps, awls, drill bits and reamers, drill guides, trays, and other general orthopedic instruments. In addition to these instructions, Anika also provides surgical technique guidebooks and animations of simulated use on the Anika website, as indicated on the package label.

2. **Warnings:**

    A. Caution: Federal Law restricts this device to sale by or on the order of a physician.
    B. This product must be inspected prior to each use and before sterilization.
    C. Never place a cannulated device over a bent or damaged guide pin.
    D. Loading this instrument or any instrument used with this device in an off-axis manner may result in breakage or bending of the instrument, drill guide or obturator.
    E. Never use a dull, bent, or damaged instrument.
    F. This product is not intended to be left in the body.
    G. Be sure to remove any debris from the cannulation of the device, as applicable, during the cleaning process.
    H. Always confirm compatibility of devices such as cannulated drill bits and reamers prior to introducing into the patient.

3. **Material:**

    A. These products are manufactured from stainless-steel, aluminum, and medical grade polymers. Stainless-steel and aluminum are radio-opaque and can, therefore, be detected with conventional X-Ray or fluoroscopy. Polymers are typically radio-lucent, so ultrasound can be used for detection.

4. **Inspection:**

    A. Inspect the device for damage at all stages of handling.
    B. If damage to the device, label, or packaging is detected, consult the manufacturer for guidance.
    C. Inspect device markings and ensure all are clearly visible.

5. **Device Lifetime:**

    A. This device is intended for multiple use. End of device life has occurred when the device fails visual and/or functional criteria.

6. **Cleaning:**

    A. Immediate rinsing and cleaning after use with an enzymatic detergent will effectively remove and prevent drying of adherent blood, tissue, etc.

B. Scrub device with a soft brush, paying special attention to the cannulation and other areas where debris might accumulate. Always avoid any harsh materials that can scratch or mar the surface of the device.
C. Rinse the device thoroughly with water following the cleaning process.

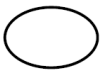
7. Sterilization:

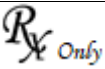
A. This product is a non-sterile item that must be cleaned and sterilized prior to use. The following table provides the recommended minimum sterilization parameters that have been validated by Anika to provide a 10^{-6} sterility assurance level (SAL):

Cycle Type	Minimum Temperature	Minimum Exposure Time (Wrapped)	Minimum Dry Time
Pre-vacuum	132°C / 270°F	4 minutes	30 minutes[1]
	134°C / 273°F	3 minutes	30 minutes[1]

[1] Drying times vary according to load size and should be increased for larger loads

8. Symbol Glossary:

Symbol	Definition	Standard Used	Ref #
	Legal Manufacturer	ISO 15223-1	5.1.1 5.1.11 5.1.3
	Authorized representative in the European Community	ISO 15223-1	5.1.2
	Use-by-date	ISO 15223-1	5.1.4
	Batch code	ISO 15223-1	5.1.5
	Catalog number	ISO 15223-1	5.1.6
	Sterilized using ethylene oxide	ISO 15223-1	5.2.3
	Do not resterilize	ISO 15223-1	5.2.6
	Non-sterile	ISO 15223-1	5.2.7
	Do not use if package is damaged	ISO 15223-1	5.2.8
	Single sterile barrier system	ISO 15223-1	5.2.11

	Double sterile barrier system	ISO 15223-1	5.2.12
	Keep away from sunlight	ISO 15223-1	5.3.2
	Keep dry	ISO 15223-1	5.3.4
	Upper limit of temperature	ISO 15233-1	5.3.6
	Do not re-use	ISO 15223-1	5.4.2
	Consult instructions for use	ISO 15223-1	5.4.3
 www.anikaifu.com	Consult electronic instructions for use (eIFU)	ISO 15223-1	5.4.3
	Patient identification	ISO 15223-1	5.7.3
	Patient information website	ISO 15223-1	5.7.4
	Healthcare center or doctor	ISO 15223-1	5.7.5
	Date	ISO 15223-1	5.7.6
	Medical device	ISO 15223-1	5.7.7
	Unique device identifier	ISO 15223-1	5.7.10
	Quantity	NA	NA
	Caution: U.S. Federal law restricts this device to sale by or on the order of a physician	21 CFR 801	801.109
	MR Conditional	ASTM F2503	Table 2

	MR Safe	ASTM F2503	Table 2
	MR Unsafe	ASTM F2503	Table 2