

## Brasseler USA Orthopedic Pin Packs Instructions for Use

### BRASSELER USA Orthopedic Pin Packs

#### Description

BRASSELER USA orthopedic pins, also known as fixation pins or anchoring pins, are made out of Surgical-grade stainless steel and are sold single use sterile and non-sterile in various diameters and lengths. Brasseler USA orthopedic pins can be smooth, fluted, threaded or partially threaded with a sharp pointed end and a blunt end.

#### Intended Use

BRASSELER USA orthopedic pins are manual surgical instruments that are designed to temporarily align, secure and fixate cutting templates, guides and other devices to bone. Orthopedic Pins should only be used by licensed medical professionals in their safe and effective use.

#### Indication for Use

BRASSELER USA orthopedic pins are to be used on patients during hip, knee, shoulder and extremity arthroplasty and trauma surgeries.

#### Contraindications

All known contraindications for surgery must be generally taken into account. These include, but are not limited to:

- Bone with insufficient bone quality or quantity as determined by a qualified professional.
- Patients that have allergies to the metal used. Before use if metal allergy is suspected appropriate testing should be conducted before treatment with the pins.
- Avoid use in patients with diseases that inhibit the healing process.

#### Precautions

- The device is to be used by authorized persons fully trained in their safe and effective use.
- In case of unexpected product anomaly, it is recommended to have back-up consumable accessories to reduce any surgical delays and to prevent prolonged or additional anesthesia exposure.
- Inspect the product packaging for damage before opening.
- Always verify sterile product is within its labeled expiration date to ensure sterility prior to use.
- Dispose of product or recycle in accordance with local laws and regulations.
- All product should be stored in an environment that prevents premature degradation. The product should be protected from prolonged exposure to direct UV light, excessive heat, and humidity.

#### Warnings

- Care must be taken not to cut through surgical gloves when handling any sharp-edge orthopedic device.
- Pins are intended for single use only. Reuse of pins may increase the risk of product damage and patient injury.
- Do not re-sterilize or reprocess pins after use. This may increase the risk of cross contamination.
- Do not use if the pins exhibit signs of corrosion or damage.
- Do not use excessive, lateral, twisting or bending forces to prevent consumable accessory failure such as bending or breakage. Exercise extra caution when used with alignment guides or cutting fixtures.
- Avoid placing pins into bone sections which are subject to high tensile or torsional stress moments in order to minimize the risk of stress fractures.
- Transcortical pin fixation is detrimental to bone strength and may be associated with increased risk of bone necrosis.
- Ensure low drilling speed to avoid excessive heat generation which may result in bone necrosis. External irrigation should be applied, if possible.

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Magnetic Resonance Imaging (MRI) Safety Statement: The effects of the Magnetic Resonance environment on the K-Wires/Steinmann Pins and Orthopedic pins have not been determined. These medical devices have not been tested for magnetic field/migration, artifacts or heating in the MRI environment.

### Cleaning and Sterilization Instructions for Non-Sterile or Open and Unused Pins

Scope	These instructions are applicable to all BRASSELER USA orthopedic pins. They are applicable before initial use.
Reprocessing Limitations	<p>Do not re-use or reprocess used consumable accessories. If a consumable is to be re-used, there is a potential for bone necrosis and cross contamination.</p> <p>Unused pins removed from original or non-sterile package:</p> <ul style="list-style-type: none"> <li>• See sterilization parameters below.</li> </ul> <p>Unused pins contaminated during surgery:</p> <ul style="list-style-type: none"> <li>• Clean pins as soon as possible to avoid drying of contaminants. Disinfecting the pins may be needed to protect personal handling of the instrument before cleaning and sterilization. If cleaning must be delayed, immerse the pins in a neutral-pH cleaning solution to prevent drying of contaminants on the instruments.</li> </ul>
Manual Cleaning Procedure	<p>Manual (Hand Cleaning) is the only validated cleaning process for the Pins.</p> <ol style="list-style-type: none"> <li>1. Rinse the soiled consumable accessory thoroughly with a large amount of lukewarm (target lower end of the 72-110°F/22-43°C temperature range) running tap water for a minimum of one (1) minute.</li> <li>2. Make an enzymatic cleaning solution such as STERIS® Prolystica™ 2x Concentrate Enzymatic Presoak and Cleaner [1/8 ounce per one (1) gallon of warm tap water] (target lower end of the 91-109°F/33-43°C temperature range).</li> <li>3. Soak the pins in the enzymatic cleaning solution for two (2) minutes, making sure the pins are completely immersed to prevent aerosolization of contaminants.</li> <li>4. Manually clean the pins using a soft-bristled brush for one (1) minute to remove soil and debris.</li> <li>5. Rinse soiled pins by immersing the pins in a sufficient volume (enough to cover the device) of lukewarm, tap water (target lower end of the 72-110°F/22-43°C temperature range) for one (1) minute.</li> <li>6. Repeat Step 5 two (2) more times for a total of three (3) rinses. Visually inspect pins for the presence or absence of residual soil and /or cleaner.</li> <li>7. Dry immediately with a clean lint-free soft cloth.</li> <li>8. Inspect for damage and replace with new pins</li> </ol>
Inspection Testing	<ul style="list-style-type: none"> <li>• Carefully inspect each device to ensure that all debris has been removed.</li> <li>• Visually inspect the device for damage/ wear that would prevent proper operation. <ul style="list-style-type: none"> <li>▪ Do not use if there is evidence of corrosion, rotary instrument interaction or other signs of damage.</li> </ul> </li> </ul>
Sterilization Warnings	<ul style="list-style-type: none"> <li>• The use of disinfecting solutions for an exterior instrument wipe will not sterilize the pins.</li> <li>• Inspect sterilized pins. If discoloration or rust is visible, do not use to avoid potential patient toxicological and/or allergic reaction.</li> </ul>
Sterilization Cautions	<ul style="list-style-type: none"> <li>• Do not re-use or reprocess used consumable accessories. If a consumable is to be re-used, there is a potential for bone necrosis and cross contamination.</li> <li>• Do not use cold sterilization solutions as these contain oxidizing agents which may cause damage to the device.</li> <li>• Do not sterilize the consumable while connected to handpiece and/or attachment as this may result in the product not being properly sterilized.</li> <li>• Wrap the instruments per AAMI recognized guidelines.</li> <li>• Follow the sterilizer manufacturer's written instructions for cycle parameters, load configuration and AAMI guidelines for steam sterilization.</li> </ul>

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- Do not clean or re-sterilize laser welded or brazed two piece pins. Failure to follow these instructions may result in corrosion, oxidization, or rusting of the product.

Sterilization

Parameters for Sterilization













Steam Sterilization Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time
Pre-vacuum (Wrapped)	270°F (132°C)	4 minutes	30 minutes
Gravity (Wrapped)	270°F (132°C)	15 minutes	30 minutes

Additional Information

These processes have been validated for a one-time sterilization as being capable of cleaning and sterilizing K-wires/Steinman Pins/Guide Wires/Orthopedic pins.

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**Glossary of Symbols**

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
<b>Rx Only</b>	Caution: Federal law restricts this device to sale by or on the order of a “dentist/physician” licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
<b>Made in</b>	Made in	N/A
	Manufacturer/Legal Manufacturer	ISO 15223-1
	Do not re-sterilize	ISO 15223-1
	Sterilize using irradiation	ISO 15223-1
	Use By Date	ISO 15223-1
	Do not re-use	ISO 15223-1
	Do not use if package is damaged	ISO 15223-1



Brasseler USA Medical, L.L.C.  
 One Brasseler Blvd.  
 Savannah, GA 31419 USA  
 800.535.6638  
 BrasselerUSAMedical.com

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