Manufactured By:
Treace Medical Concepts, Inc.
100 Palmetto Park Place
Ponte Vedra, FL 32081
904-373-5940
www.treace.com

Treace Medical Concepts Patient Specific Instrumentation System Instructions for Use

Description

The Treace Medical Concepts (TMC) Patient Specific Instrumentation (PSI) System includes patient specific single use cutting guides generated from a patient's CT scans following a surgeon's prescription.

Indications for Use

The TMC Patient Specific Instrumentation System is intended to be used as a surgical instrument to assist in pre-operative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot and ankle for adult and pediatric patients 12 years of age and older. The TMC Patient Specific Instrumentation System cutting guides are intended for single use only.

Contraindications

While the TMC Patient Specific Instrumentation System does not have specific contraindications, the following general contraindications include the following:

1. Infection
2. Patient conditions including blood supply limitations, obesity, and insufficient quality or quantity of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to use of bunion blueprint guides and associated surgical tools.
5. If the patient's bone anatomy changed since the date of imaging, the patient specific cutting guides should not be used.

Warnings

For safe and effective use of the TMC Patient Specific Instrumentation System, the surgeon should be familiar with the recommended surgical technique for this device. In every case, accepted surgical practices should be followed in postoperative care. Patient sensitivity to instrument materials should be considered and assessed prior to surgery. In the case of pediatric patients, the cut guides should only be used in adolescents (>12-21 years of age). The physician must consider the patient pathology evolution between CT scan date and the surgery date to validate the imaging data prior to surgery. If the patient's bone anatomy changed since the date of imaging, the patient specific cutting guides should not be used.

Precautions

Use of a cut guide or instrumentation from other devices may result in failure to adequately, correctly, or fully complete cuts and correction. Single use instruments must never be reused. Previous use and stressed may have created imperfections that could lead to device failure. Single use devices will degrade after single use potentially resulting in failure during reuse.

DO NOT permanently implant K-wires as they can lead to tissue damage. Use of K-wires allows the surgeon to provisionally secure the guide and bone fragments.

Do NOT permanently implant instruments including cut guides, drills, k-wires, or other instruments.

Potential Adverse Events

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations specific to the use of metallic cut guides and pins. General surgical risks should be explained to the patient prior to surgery:

- Infection or adverse reaction to a foreign body
- Pain, discomfort, abnormal sensations following tissue dissection or use of a bone saw

Packaging, Cleaning, Sterilization

- Cut guides are supplied clean and non-sterile and must be sterilized prior to use (see below for instructions). The cut guides may be cleaned prior to use (see below for instructions). Ensure that all packaging is removed prior to cleaning and sterilization.

Manual Cleaning

Note: Cut guides must be removed from trays or cases throughout the cleaning.

1. Rinse the device thoroughly under running warm (35-40°C) tap water for a minimum of 1 minute. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from device.
   Note: Pay special attention to all holes and crevices.
2. Soak the device in a neutral enzymatic cleaner (e.g. Enzol® or equivalent) for a minimum of fifteen (15) minutes. Components must be fully immersed in the cleaner. Ensure that there are no air pockets in the hard-to-reach areas such as lumens. Follow the cleaner manufacturer's instructions or cleaner preparation and maximum exposure time.
3. Thoroughly rinse the components with warm (35-40°C) water for a minimum of 1 minute. While rinsing, use soft bristle brushes, a syringe to clean out lumens, holes, and other challenging features.
4. Manually scrub the device thoroughly in freshly prepared, clean, neutral pH enzymatic cleaner using soft bristle brushes or syringes. All lumens, holes, and crevices, and challenging features should be thoroughly scrubbed. Expose all areas to the cleaner.
5. Rinse the device thoroughly with deionized water; using a syringe to flush lumens, holes, and other hard to reach or challenging features for a minimum of 1 minute.
6. Visually inspect device for soil. Repeat the cleaning procedure until no visible soil remains on the components.
7. Perform a final rinse on the components using deionized water for a minimum of 1 minute.
8. Dry the components using clean compressed air or a soft, lint free, clean cloth.

Automated Cleaning

Device pre-cleaning shall be performed prior to cleaning through the automated washer.

Note: Cut guides must be removed from trays or cases throughout the cleaning.

Pre-Cleaning:

1. Soak the device in tap water for a minimum time of 10 minutes. While soaking, brush the instrument using a soft bristle brush to loosen and remove as much visible soil as possible from instrument.
   Note: Pay special attention to all holes and crevices.
2. Using a syringe, flush all lumens (if present) for 30 seconds with tap water.
3. Brush under tap water with a soft bristled brush for a minimum of 40 seconds or until all residues are removed.
4. Rinse the device under tap water for a minimum of one (1) minute.
5. Visually inspect device for soil. Repeat steps 1 through 4 if visible soil remains.
6. Dry the device using clean compressed air or a soft, lint free, clean cloth.

Automated Washer Instructions:

Washer should be compliant to requirements established by ISO 15883.

Note: An automated wash cleaning cycle has been validated by Treace Medical Concepts, Inc. as being capable of achieving clean medical devices; however, automated wash design and performance can affect the efficacy of the process. Healthcare facilities should verify the process that they use, employing the actual equipment and operators that routinely process the devices.

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	Cleaning Procedure		
	Automated Cleaning Criteria		
Cycle	Time	Temperature	Detergent & Concentration
Pre-rinse	3 min	Cold Water	N/A
Enzymatic Wash	5 min	131 °F (55°C)	Enzymatic Detergent (e.g. Enzol® or equivalent)
Wash 2	3 min	150 °F (65.5°C)	Neutral Detergent (e.g. Prolystica® 2X concentrate or equivalent)
Rinse	3 min	Warm water (> 110 °F (> 43°C))	N/A
Drying	Dry the outside of the device using the drying cycle of the cleaning equipment. If necessary, the device can be dried by hand with a sterile lint-free cloth. Compressed, filtered air can be used for devices with lumens.		

Sterilization Procedures

The cut guides are supplied clean and non-sterile. The Cut Guides must be sterilized separately from other instruments.

Note: An autoclave cycle has been validated by Treace Medical Concepts, Inc. as being capable of achieving sterile medical devices; however, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should verify the process that they use, employing the actual equipment and operators that routinely process the devices.

Method	Pre-vacuum steam sterilization
Wrapping	Wrap tray and/or devices in two layers of FDA-cleared sterilization wrap
Temperature	270°F (132°C)
Exposure Time	4 minutes
Drying Time	30 minutes (minimum, in chamber)

Method	Gravity steam sterilization
Wrapping	Wrap tray and/or devices in two layers of FDA-cleared sterilization wrap
Temperature	270°F (132°C)
Exposure Time	15 minutes
Drying Time	15 minutes (minimum, in chamber)

Caution: Federal law restricts this device to sale by or on the order of a physician.

For product experience feedback, call 904-373-5940 or email pe@treace.net.