Lento PST® System

Hospital Cleaning, Sterilization, and Disposal

Document #: LB-75-02-001

Model: Release B

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Author:

Signature: _____ **Date** 9/5/19

Reviewed and Approved by:

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Warnings:

- The Lento PST® System has not been evaluated in a pediatric population therefor performance in such cases is unknown.
- The Lento PST® System is a prescription only medical device.
- The Lento PST® System is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on education, training and experience of the practioner.
- Lento PST® System only provides and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI image sources.
- The Lento PST® System does not provide an absolute or only solution plan for joint replacement surgery, it only documents one possible approach, no surgical philosophy is recommended.
- These are patient specific, single use, disposable instruments.
- Do not attempt to reuse, recondition or re-sterilize.
- Do not alter the custom guides in any way.
- Lento PST® System guides are to be used by a surgeon trained in the use of personalized instrument surgery (custom guides).
- Be aware that these patient specific instruments have been manufactured based of MRI scans of the patient. If the patient's anatomy has changed significantly since the time of the MRI scan, the instruments should not be used.
- The instruments should be properly cleaned and sterilized before use. Do not use if the instruments are broken, cracked or if debris is present.
- The guides and their package are provided ***non-sterile only***.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

Cautions:

- The use of aged (>3 months) MRI image files is not recommended. Accuracy of planning and guide fit will diminish with evolving or changing disease processes.

Precautions:

- Use only MRI data of recent origin obtained per established Lento PST® System designated MRI protocols.
- Care should be taken to minimize excessive heat buildup due to friction between the PSI instruments and other instrumentation, such as drills. Excessive heat buildup can lead to deformation of the Lento PST® System guide.

- Do not place heavy instruments on top of the Lento PST® System guides during sterilization.

Limitations

- Metallic implants in or near the affected joint are known to interfere with the MRI images and may yield unreliable or useless images.
- The Lento PST® System provides an estimate of implant sizing only. Exact implant size can only be determined during surgery and may differ from sizes projected during planning. Most estimated implant sizes will typically fall within one size of estimation.
- The Lento PST® System is not for use in planning revision/replacement surgery in persons already having implants in the affected joints.
- Digital x-ray data is not acceptable for guide production the files must be MRI images.

Contra-indications

- Do not use in patients with active infection of the knee joint area.

NOTICE: Lento PST® Cutting Guides are intended to assist in the execution of the designated joint replacement surgery and can only be used in association with Lento PST System web software application. The guides are not reusable or transferable to any other person or surgery type.

Help Desk: If this document does not address your question, please contact Lento, Inc. by:

Telephone: United States telephone support +1 (510) 413-3230

Internet: If you have access to the Internet, you can reach the Help Desk support team via: World Wide Web at http://www.lentomedical.com

Manufacturer:
Lento Medical, Inc.
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CE 2460

The following organization is the Authorized Representative for the Lento PST® System:

EC REP

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These services are available free of additional charges to all registered customers.

Indication for Use: The Lento PST® Cutting Guides are for clinical use as a template or guide for use in orthopedic surgery to assist the surgeon in selecting or positioning orthopedic implants and guiding the marking of tissue before cutting or pining for a specifically named patient.

CAUTION: United States Federal law restricts this device to sale by or on the order of a Physician

Acknowledgements:

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Benjamin Soo-Il Song, M.D., Diplomat American Board of Orthopaedic Surgery

Cleaning and Sterilization

Whenever possible, an automated method of cleaning should be used. The automated cleaning process is more reproducible and reliable than manual cleaning methods. This method also affords the staff less exposure to the cleaning agents used.

Whichever method is used, staff should use suitable personal protective equipment (PPE) and follow existing hospital procedure for this activity. In addition, the instructions provided by the manufacturer(s) of the cleaning agent(s) concerning correct handling and use of the product should be reviewed.

Please note that certain cleaning solutions may discolor the devices if left to soak for prolonged periods. Staining may happen if rinsing after cleaning is inadequate. Cleaning agents formulated or offered as safe for plastic or polymer devices should be used to clean the templates if possible. For soaking and hand washing, enzymatic cleaners and manual detergents should be used. For automated cleaning, enzymatic and/or neutral detergents may be used if permitted by hospital procedures and equipment brand.

Please follow the indications, instructions, and warnings provided by the manufacturer(s) of the cleaning agent(s) or equipment used. Lento Medical, Inc. does not recommend specific cleaning agents or brands. Examples of typical cleaning agents available include:

- Endozime AW,
- Getinge® Renuzyme WR,
- Getinge® High Foam Manual Cleaner,
- Steris® Klenzyme, and
- Steris® NpH-Klenz.

WARNING: The Lento PST System Cutting Guide may not withstand exposure to automated cleaners operating at 285℃ (141℃) and above or which use live-steam jets as cleaning features.

The minimum sterilization parameters are:
Place device in a 7”x12” peel pouch - Mylar type (suggested)
Sterilizer Type: Pressure Vacuum (Pre-Vac) Sterilizer
Exposure (Holding time): 3 minutes

Temperature: 275℉ or 135℃ (EU)
Pressure: 2-15 PSIA

After sterilizing, the device(s) should be allowed to cool to room/ambient temperature or until adequately cooled for safe handling.

Disposal

The Lento PST System Guides are constructed from recognized biocompatible materials and do not represent hazardous substances in terms of disposal. Once used, the devices must be considered biohazard due to their exposure to biological fluids of a patient. Disposal must be conducted in accordance with state local and hospital policy for handling biohazard materials.

In the event the devices are to be returned to Lento Medical and the devices are unused, no precautions are necessary and standard shipping may be used. However, if the devices have been used, they are considered biohazard and must be cleaned and sterilized before returned. Refer to the “Cleaning and Sterilization” section of this document for instruction on how to prepare the device for return.