# PtoleMedic System

# Hospital Cleaning, Sterilization, and Disposal

## Document #: LB-75-02-001

## Model: Revision B

## November 2, 2020

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**Warnings:**

- The PtoleMedic System has not been evaluated in a pediatric population therefor performance in such cases is unknown.
- The PtoleMedic System is a prescription only medical device.
- The PtoleMedic System is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on education, training and experience of the practitioner.
- PtoleMedic System only provides, and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI image sources.
- PtoleMedic 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.
- The surgical 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 surgical 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 PtoleMedic System designated MRI protocols.
- Care should be taken to minimize excessive heat buildup due to contact between the PtoleKnee Surgical Guides and other metallic instrumentation, such as drills. Excessive heat buildup can lead to deformation of the surgical guides.
- Do not place heavy instruments on top of the surgical 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 PtoleMedic 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 PtoleMedic 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:** Surgical Guides are intended to assist in the execution of the designated joint replacement surgery and can only be used in association with PtoleMedic 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 Medical Innovation, 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/contact/

**Manufacturer:**

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The following organization is the Authorized Representative for the PtoleMedic System:

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

***Indication for Use:*** The Surgical 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:**

Lento Medical Innovation, Inc. acknowledges the assistance of the following orthopedic surgeon for the expertise, guidance and time devoted to the development of the surgical protocol:

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

## Cleaning and Sterilization

The sonication cleaning process is more reproducible and reliable than manual cleaning methods. This method also affords the staff less exposure to the cleaning agents used. The cleaning method laboratory validation utilized a SonicWise Ultrasonics; Model: SW-308 sonicator.

## Ultrasonic Cleaning

The preferred method of guide cleaning is ultrasonic (Sonicator) cleaning. This method is the most efficient and effective available today. Ultrasonic cleaning is up to 16 times more efficient than manual cleaning alone. Place instruments in the Sonicator for 15 minutes using a neutral pH enzymatic ultrasonic cleaning solution.

1) Before placing into the ultrasonic unit, rinse the instruments in warm running tap-water making sure to flush all channels and slots thoroughly.

2) Fill the Sonicator with fresh enzymatic cleaning solution* prepared according to manufacturer's instructions. A neutral pH ultrasonic solution should be used. Lento Medical Innovation, Inc. does not recommend a specific brand of enzymatic cleaner**.

3) Make sure instruments have plenty of room. Don't overload the ultrasonic cleaner. Sonicate the guides separately from all other instruments or articles.

4) Upon completion of the cycle, remove the guides immediately and rinse them under warm running tap-water as before.

5) Dry instruments thoroughly with a non-linting towel. Use compressed air to clear rinse water from all channels and slots. Ensure that no moisture remains on the Guides.

* ***Use distilled water or tap water with a neutral pH ultrasonic solution when filling the ultrasonic cleaner. Never use a manual soap in the ultrasonic cleaner and always follow proper dilution.***

** ***This cleaning procedure was validated using Miltex Surgical Instrument Cleaner (Phosphate free) neutral pH 7.05-7.65.".***

Cleaning validation was obtained using an FDA cleared cleaning agent.

**<u>WARNING:</u> The Surgical Guides may not withstand exposure to automated cleaners operating at 285°F (141°C) and above or which use live-steam jets as cleaning features.**

**Use only FDA cleared sterilization pouches or wraps. Place each guide in a 7"x12" peel pouch - Mylar type (suggested)**

**Validated sterilizer parameters are:**
**Sterilizer Type:** Steam, Vacuum (Pre-Vac) Sterilizer
**Exposure (Holding time):** 3 minutes
**Temperature:** 275°F or 135°C (EU)
**Drying Time:** 32 Minutes

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

**Disposal**

The Surgical 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 Innovation 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 return. Refer to the "Cleaning and Sterilization" section of this document for instruction on how to clean & sterilize the device for return.