



Lento PST® System

Instructions for Use - Template Design

Approval (Surgeon)

Software Release Version 1.3.x

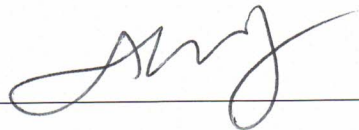
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Model: Release B

September 5, 2019

Author:

Signature:



Date

9/5/2019

Reviewed and Approved by:

Signature:



Date

9/5/2019

These instructions are intended to guide the surgeon in the surgical planning and template design, review and approval stage for an order of the Lento Medical PST® System guides. Approval is provided online through the Lento Medical web portal (www.lentomedical.net).



Manufacturer's Contact Address:

Lento Medical, Inc.
15110 Northwest Freeway, Suite 150
Houston, TX 77040 – USA
+1 (510) 413-3230



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



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De Tweeling 20-22
5215 MC's - Herrogenbosch
The Netherlands
Tel.: +31-13 5479300
Web: www.healthlinkeurope.com

Introduction

Lento Medical PST® System *web-based software* offers a simplified Total Knee Replacement (TKR) surgery planning interface. Surgical planning software is widely available but is generally PC or local server based. The use of such programs tends to be time consuming, expensive and requires frequent updating and/or IT maintenance. The Lento Medical PST System offers “**log-on-and-use**” surgical planning tools and custom made cutting guide creation. And the system is **low-to-no maintenance** requiring no IT support to install, use or maintain. The Lento Medical PST® System web-based software provides direct, focused assistance on setting angles, rotation, cut plane, offsets and implant sizing as appropriate to TKR surgery.



Warnings:

- The Lento Medical PST® System has not been evaluated in a pediatric population therefore performance in such cases is unknown.
- The Lento Medical PST® System software is a prescription only medical device.
- The software is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on education, training and experience of the practitioner.
- Surgical planning software only provides and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI/CT image sources.
- The software does not provide an absolute or only solution plan for joint replacement surgery, it only documents one possible approach, no surgical philosophy is recommended.
- The use of the software on mobile platforms, such as Google Android, Apple iPhone, or similar tablet-type devices has not been validated and is not recommended at any time.
- These are patient specific, single use, disposable instruments.
- Do not attempt to reuse, recondition or re-sterilize.
- Do not alter the instruments in any way.
- Lento Medical 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 before sterilization. Do not use if the instruments are broken, cracked, or when loose powder is present.
- The instruments in the package are provided non-sterile.
- The instruments in the package must be sterilized prior to use.
- 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 Medical 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 PSI instrument.
- Do not place heavy instruments on top of the PST System guides instruments during sterilization.

**Limitations**

- Metallic implants in or near the affected joint are known to interfere with the MRI images.
- Provides estimate of implant sizing only. Optimal 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 software is not for use in planning revision/replacement surgery in persons already having implants in the affected joints.
- DICOM to JPEG file creation – The use of planning images based on the JPEG image format limits some file attributes encoded with the original DICOM images. For instance, some information contained in the DICOM header including image manipulation functions like pan, zoom, full gray scale control, contrast adjustment and pixel resizing are limited or unavailable.
- Digital x-ray data is not acceptable for planning purposes; the files must be MRI images.

**Contra-indications**

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

User System Requirements

1. High speed internet access
2. A color monitor or display with VGA image display capabilities with 1280 x 800 resolution (recommended)
3. A mouse, touch pad or similar input device to interact with the surgery case
4. A keyboard (virtual or physical) for text input
5. A PC/Workstation w/1GB of RAM or more capable of running Windows or Mac OS
6. A Web Browser, (Internet Explorer, Firefox, Google Chrome or Safari)

Indication for Use

The Lento Medical PST® System is a software interface and image manipulation system used to transfer DICOM images from a Magnetic Resonance Imaging (MRI) system.

The Lento Medical PST® System creates a surgical plan and produces a **custom surgical instrument** intended to assist the surgeon in the orientation and placement of Total Knee Replacement (TKR) components intra-operatively by guiding the marking of bone or tissue before cutting.

NOTICE: The Lento Medical PST® System software does not utilize any compression techniques or technology when accepting, storing or viewing DICOM images.

NOTICE: *Software Anomalies.* The Lento Medical PST® System software supports the following Web Browsers, Internet Explorer (Ver 9.0) or newer, Firefox (Ver 15.0) or newer, Google Chrome (Ver 25.0) and Safari (Ver 4.0) or newer. Such browsers may be used with various operating systems, including those supporting Windows OS (XP, 7, Vista) or newer or Mac OS X (Ver 10.0) or newer.

Depending on your browser or operating system your screen may look slightly different depending on the software environment. This may include available fonts, spacing between graphical user interface (GUI) components, and some other minor appearance items.

NOTICE: The Lento Medical PST System Web software does not interact directly with DICOM generating equipment (PACS devices). The image files needed by the Lento Medical PST® System Web software originate from the MRI/CT center as DICOM files which are transferred to the company server by Imaging Center personnel using DICOM compliant processes. File transfer protocols or file transfer requests are not generated or provided.

NOTICE: The Lento Medical PST® System Surgical Planning Software program does not interact with or affect DICOM image source equipment (PACS devices).

Updates: For updates to this document, please contact the Help Desk support team.

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

Telephone: The Help Desk and Customer Service support teams can be reached via:
United States and Canada during normal operating hours +1 (510) 413-3230.

Company URL: <http://www.lentomedical.com>

Lento Medical PST System URL: <http://www.lentomedical.net>

1. Log In

Lento Medical Admin or Sales personnel will assist the surgeon with registering an account for the Lento Medical web portal. Once a username and password is created, the surgeon will use the information to log in.

- a. Enter Username
- b. Enter Password
- c. Click “Login” button

Welcome to Lento Medical Inc.

Username:

Password:

2. Surgeon Landing Page

The surgeon landing page will appear listing all active cases for surgeon view.

The status of a case that requires surgeon approval will show “Surgeon Approval Pending.”

The Surgeon can double click the case number and the patient case page will appear.

Jane Doe Surgeon

Last Name
Doe
Middle Name
N/A
First Name
Jane

Email Address
akim.orthomade@gmail.com
Phone
1234567890
Fax
N/A

Office Name
OM Office
Office Address
402 Kato Terrace, Fremont, CA 94539

Cases

Case #	Surgeon	Patient	DOPO	DOS	DOB	Type	Side	Notes	Status
K27915R	Jane Doe	John Smith	Aug. 11, 2016	Oct. 15, 2016	June 16, 1953	TKA	R		Surgeon Approval Pending

3. View Surgeon Planning Reference

From the patient case page, surgeon will need to click “View Surgeon Planning Reference.”

K27915R John Smith Surgeon Approval Pending

<p>Surgeon ✎</p> <p>Jane Doe</p> <p>Email Address akim.orthomade@gmail.com</p> <p>Phone 1234567890</p> <p>Fax N/A</p> <p>Office Name OM Office</p> <p>Office Address 402 Kato Terrace, Fremont, CA 94539</p>	<p>Patient</p> <p>John Smith</p> <p>Age 63 Gender Male</p> <p>DOPO Aug. 11, 2016</p> <p>DOB June 16, 1953</p> <p>DOS Oct. 15, 2016</p> <p>Surgery TKA</p> <p>Side Right</p>	<p>MRI Center</p> <p>OrthoMade MRI Center 1234 ABC AVE, Fremont, CA 95000</p> <p>Phone 5105551234</p> <p>Fax 5105551234</p>
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Note

No notes.

<p>Angela Distributor Distributor ✎</p> <p>Phone No phone provided</p> <p>Email Address No email provided</p> <p>Office Address 7944 Angela Distro Ln., Suite 269, Pittsburgh, PA 15255</p>	<p>Surgeon Preferences ✎</p> <p>Surgeon Jane Doe</p> <p>Patient John Smith</p> <p>Implant None</p> <p>Alignment None</p> <p>Requirements None</p> <p>Ship To: OM Office</p>	<p style="text-align: right; background-color: #0056b3; color: white; padding: 5px; border-radius: 3px;">View Surgeon Planning Reference</p>
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Case Files

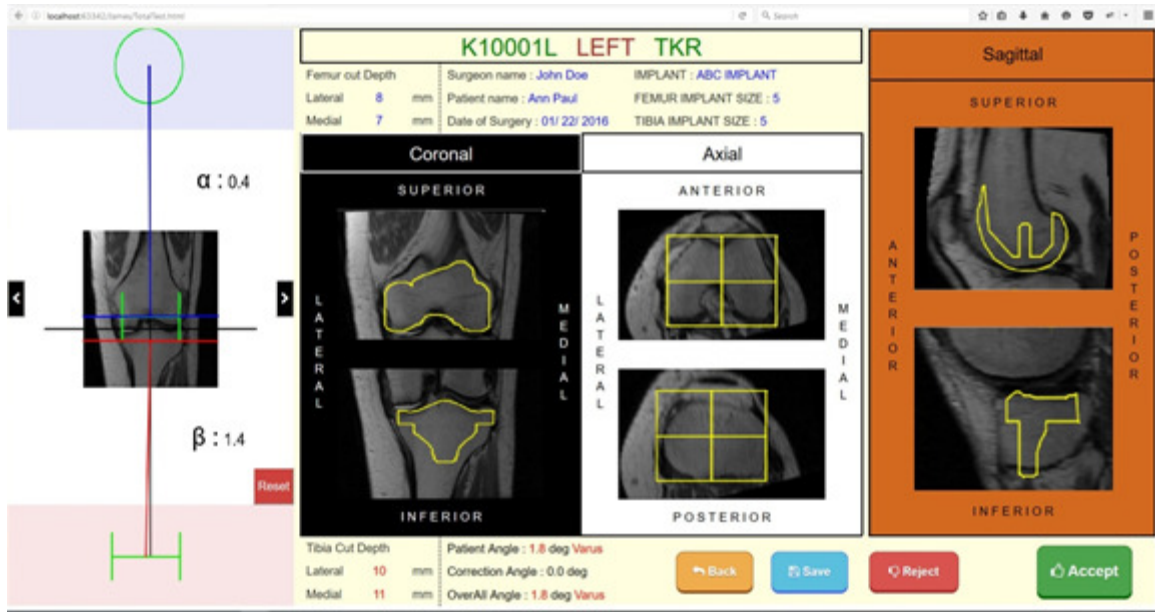
MRI Data

[K27915R_mri](#)
23.0 MB

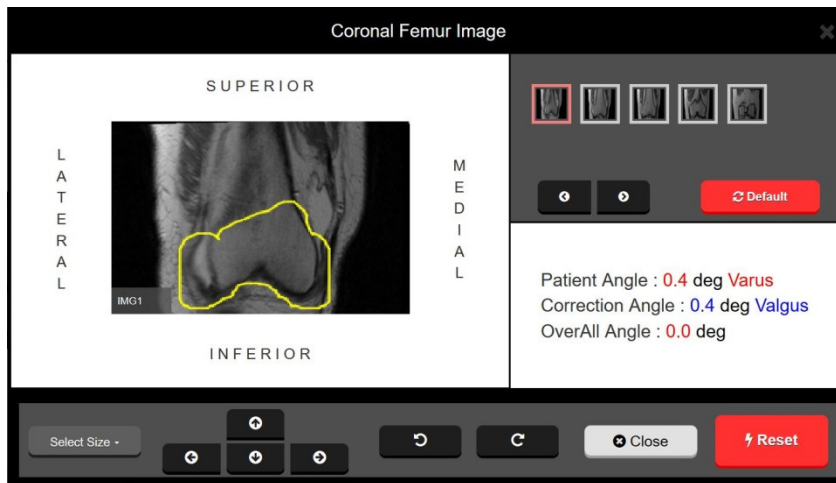
Surgeon will be directed to the “Surgeon Template Design Approval” Page

4. Surgeon Template Design Approval Page

On this page, surgeon will have the option to view each coronal, sagittal, and axial view of the MRI surgical planning.



Each Coronal, Axial, and Sagittal view will be enlarged by double clicking, showing as below.

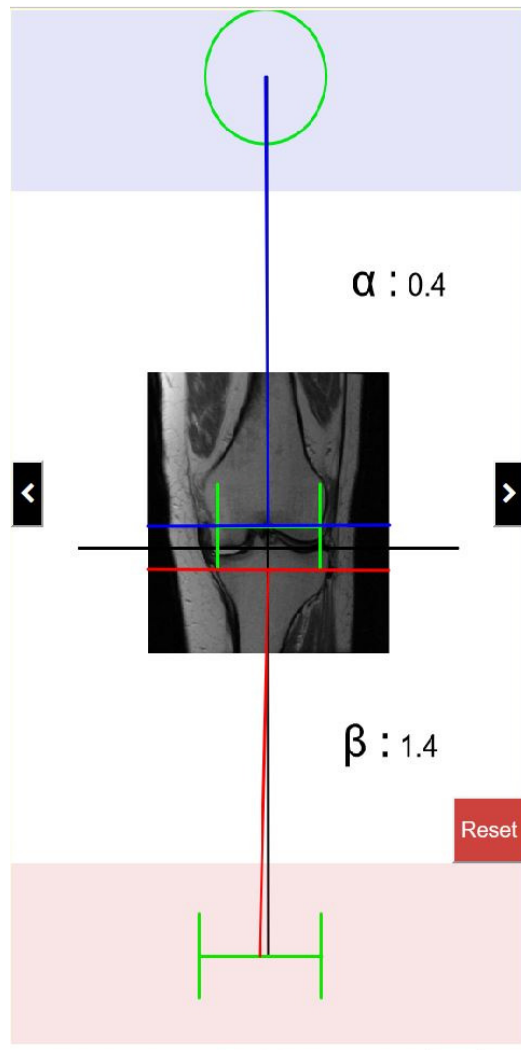


Select size will have drop selection of implant (size 1 to 8).

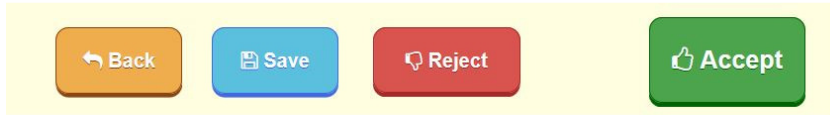
Each arrow button will move implant positioning (left, right, up, and down)

Rotate arrow will rotate the implant by 3 degrees.

The overall limb alignment may be adjusted by clicking the right or left arrow on either side of the knee graphic image. The circle at the top of the graphic represents the center of the femoral head and the brackets at the bottom represent the center of the ankle joint. Each right or left arrow click adjusts the varus/valgus angle of the knee 0.5 degree or 0.5mm, max +/- 5 degree or mm. The knee image is moved medially or laterally while maintaining the upper and lower boundary area within the femoral head and the median of the ankle. The resection lines of the rectangular resection box remain parallel to the floor.



OMM shall display a button labeled undo, a button labeled save, a button labeled save and a button labeled reject.



If the user presses the back button, OMM shall discard any saved changes and restore the original values.

If the user presses the save button, OMM shall save the current values selected. If the user logs out, the last values shall be saved on the database. OMM shall restore the saved value upon return. The order status shall remain pending review.

If the user presses the reject button, OMM shall reject the entire plan. The user shall not be allowed to continue and sets the order status to “needs reprocessing”.

If the user presses the accept button, OMM shall accept the current planning values. The user shall not be allowed to change the values after accept