

ILLUMINoss Photodynamic LED Light Curing System

SY-2100-01

Quick Start Guide

ILLUMINoss
Minimally Invasive Fracture Repair



The attached is not a replacement for the entire ILLUMINoss Photodynamic LED Light Curing System Instructions for Use Manual. Please read the Instructions for Use Manual PN 900785 prior to use. For detailed procedural information including Indications, Warnings, Cautions, Risks & Contraindications, visit www.illuminoss.com/us/ifu

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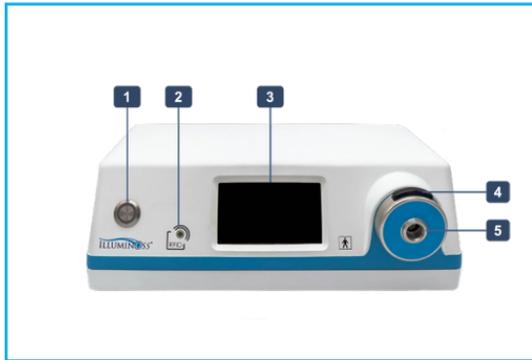
Important: Read Before Clinical Use

With the set up of any equipment brought into the hospital for use, it is important to set up and activate the LED Console prior to the start of the clinical procedure to ensure the correct operation and functionality of the unit.

Conformation of functionality of the LED Console prior to the start of the clinical procedure reduces risk, ensures that wall power connections are functional, negates potential extended procedural times and permits the exchange of equipment or alteration of clinical treatment methods should it be deemed necessary.



LED Console Parts Diagram



LED Console Front

1. Activation Button
2. RFID Timer Card Target
3. (LCD) Touchscreen
4. Light Fiber Insert / Release Button
5. Nosecone



LED Console Rear

6. Fan
7. Main Power Switch
8. Earth Ground
9. Power Cord Attachment & Power Cord
(not pictured)

Additional Parts (Within the Implant Kit)



1. RFID SYMBOL
2. Set Time (Seconds)
3. Light Fiber Hub

Clinical Use Instructions



Step 1: Placement

- I. Place LED Console on OR stand.
- II. Move stand to side of surgical site.

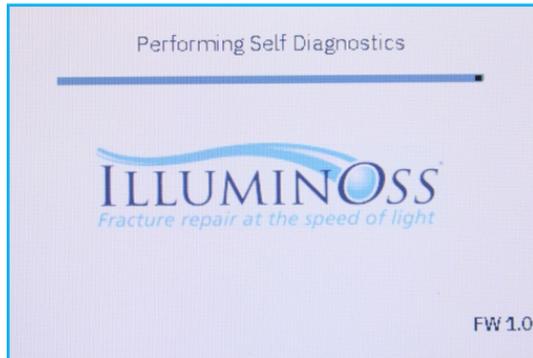


Step 2: Power LED Console

- I. Plug in LED Console.
- II. Turn on Main Power Switch (rear).
- III. Press blue blinking Activate Button (front).

Note: The LED Light Console should be turned on and functional prior to the start of the surgical procedure

Clinical Use Instructions



Step 3: Setup

- I. System runs Self Diagnostics.



Step 4: Set Cure Timer

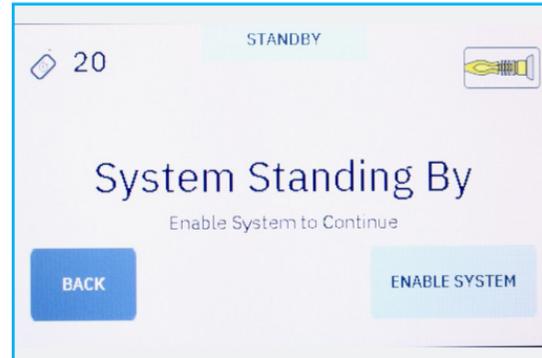
- I. Obtain Timer Card from Implant kit.
- II. Hold Timer Card to blinking green Target (front).
- III. Confirm cure time on Touchscreen and press "Accept".

Clinical Use Instructions



Step 5: Light Fiber Insertion

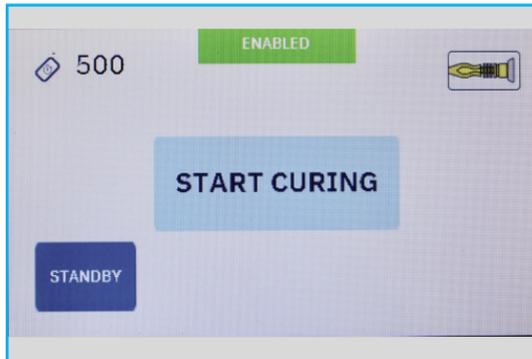
- I. Grasp the Nosecone Holding the Light Fiber Insert / Release Button down.
- II. Insert the Light Fiber into Nosecone until resistance is felt.
- III. Correct insertion of the light fiber will change the screen to STANDBY



Step 6: Standby

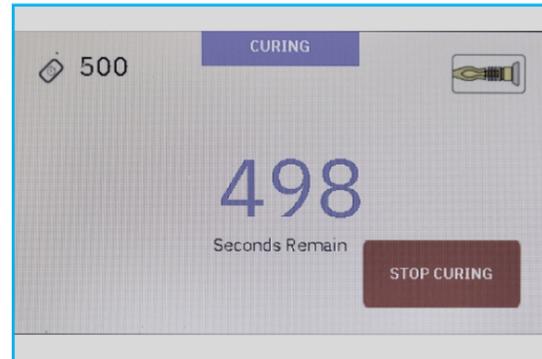
- I. When implant is in position and ready to be cured, press "Enable System," on the Touchscreen.

Clinical Use Instructions



Step 7: Start Curing

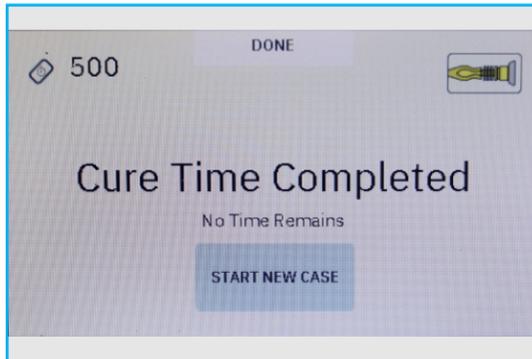
- I. The status changes to "Enabled" and the user may initiate curing
- II. Press "Start Curing" to begin curing cycle.



Step 8: Curing Cycle

- I. Light is emitted from the LED Console and curing time remaining is displayed.

Clinical Use Instructions



Step 9: Complete Curing

- I. Once the curing cycle is complete the system returns to Standby.
- II. The user may start a new case or proceed to disassembly & cleaning.

Disassembly & Cleaning



Step 1: Remove Light Fiber

- I. Press & hold Light Fiber Insert / Release Button.
- II. Remove Light Fiber.



Step 2: Power Down

- I. Press Activation Button twice to deactivate (front).
- II. Turn off Main Power Switch (back).
- III. Unplug LED Console.

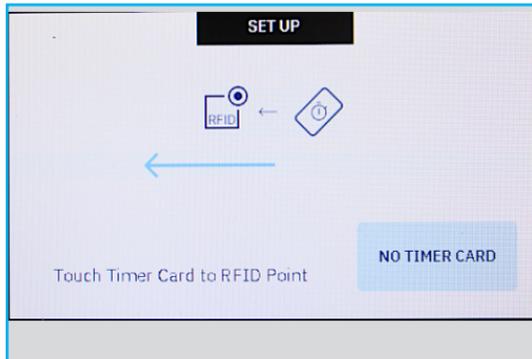
Disassembly & Cleaning



Step 3: Clean & Store

- I. Clean with Low Level Disinfectant (LLD) wipes.
- II. Place all components in travel case & store the system.

Troubleshooting | No Timer Card



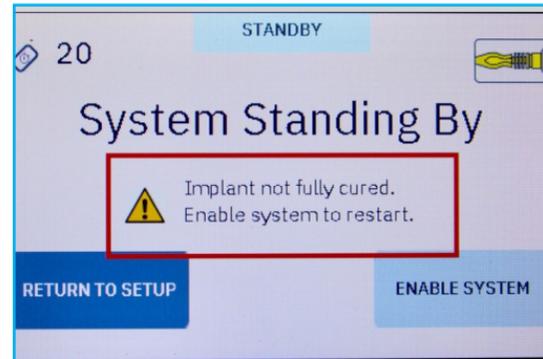
- I. Press "No Timer Card" button.
- II. System defaults to max curing time (1000 seconds).

Troubleshooting | Cancel Curing



Step 1: Cancel Curing

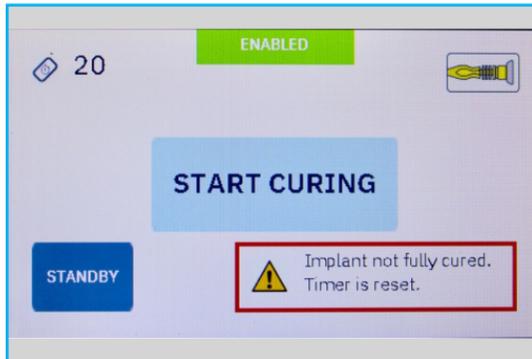
- I. Press "Stop Curing" button.
- II. Press "Stop Curing" a second time to confirm cancellation.



Step 2: Standby

- I. Once the curing timer is stopped, the system returns to Standby.
- II. Pressing "Enable System" allows the user to leave standby mode.

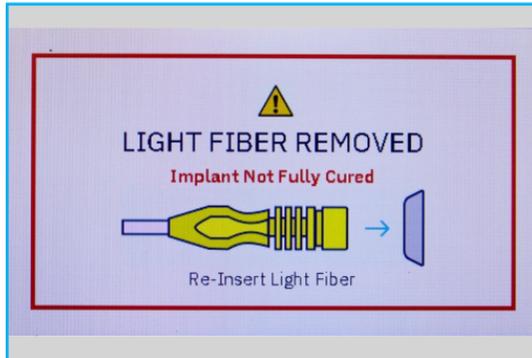
Troubleshooting | Cancel Curing



Step 3: Restart Curing

- I. The curing timer is automatically reset to the full duration.
- II. Press "Start Curing" to restart the curing process.

Troubleshooting | Light Fiber Removed



Step 1: Removal Warning

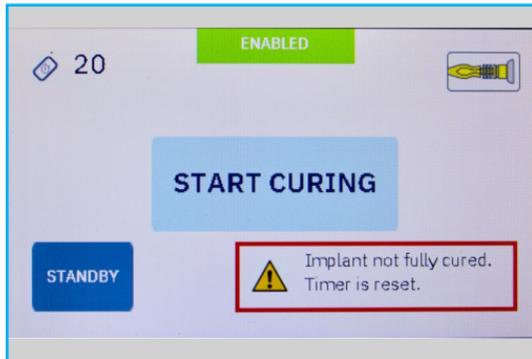
- I. If the Light Fiber is disengaged while the implant is being cured, curing will immediately stop and the system will return to Standby mode.



Step 2: Standby

- I. Once the curing timer is stopped, the system returns to Standby.
- II. Pressing "Enable System" allows the user to leave standby mode.

Troubleshooting | Light Fiber Removed



Step 3: Restart Curing

- I. Press "Start Curing" to restart the curing process.

For a complete list of all System Errors and Trouble Shooting guide, please refer to the Operating Manual 900785

Cautions & Warnings

Please read the Instructions for Use Manual PN 900785 prior to use for detailed procedural information including Indications, Warnings, Cautions, Risks & Contraindications. This IFU can be found with the LED Light Box, and also here: www.illuminoss.com/us/ifu



MRI SAFETY INFORMATION

MR Conditional

MRI modeling and physical testing were performed to consider the entire family of the IlluminOss Photodynamic Implant (4-mm to 22-mm in diameter and lengths from 30- to 280-mm).

Every version of the IlluminOss Photodynamic Implant Bone is MR Conditional. For complete details on MRI scanning parameters please review the Instructions for Use (900971), Surgical Technique Guides or visit the IlluminOss Web Site.

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For detailed procedural information including indications, warnings, cautions, risks & contraindications, visit www.illuminoss.com/us/ifu