
FlexCell
Installation and Setup Guide
for the Prosthetist
infinite
biomedical technologies

This document provides information for the prosthetist that will be installing FlexCell.

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Langenhagener Str. 71
30855 Langenhagen
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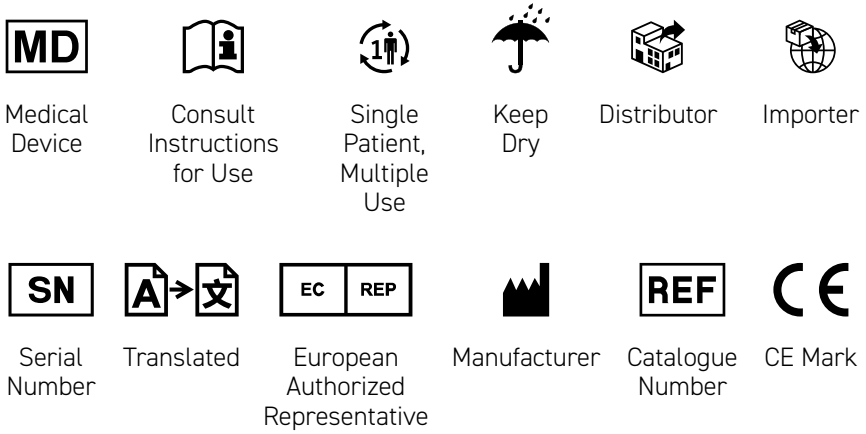
LEGEND OF SYMBOLS USED



Medical Device | Consult Instructions for Use | Single Patient, Multiple Use | Keep Dry | Distributor | Importer

Serial Number | Translated | European Authorized Representative | Manufacturer | Catalogue Number | CE Mark

This symbol is used throughout the guide to indicate important cautionary information. Text following this symbol should be read carefully.

℞ Only — Caution: Federal law restricts this device to sale by or on the order of a prosthestist.

FlexCell

INSTALLATION AND SETUP GUIDE FOR THE PROSTHETIST

Thank you for choosing FlexCell to help your patient better power their prosthesis. Whether you're retrofitting FlexCell into your patient's existing prosthesis or you're building a new prosthesis from the ground up, this guide will introduce you to FlexCell and help you install the system.

Have any questions? We're happy to help. Call us or send us an email.

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support@i-biomed.com

INTENDED USE

The FlexCell system is intended to provide power to components in a prosthesis.

INDICATIONS FOR USE

The FlexCell system is intended for use with an upper-limb myoelectric prosthesis.

CONDITIONS FOR USE / PATIENT TARGET GROUP

FlexCell is intended for use on one patient only, for users with unliteral or bilateral amputation, hand, forearm and upper arm amputation or dysmelia.

Use of the product by another person is not approved by the manufacturer. Installation of the system should be performed exclusively by a licensed prosthetist or technician. Any unauthorized handling or installation of FlexCell could void its warranty.

Table of Contents

1 Meet FlexCell

The FlexCell system is intended to power upper-limb prosthetic devices. The system consists of a charging port with an on/off button, a charger, and flexible lithium-polymer gel batteries. The flexibility of the batteries allow practitioners to conform them to the inner surface of the prosthesis shell.

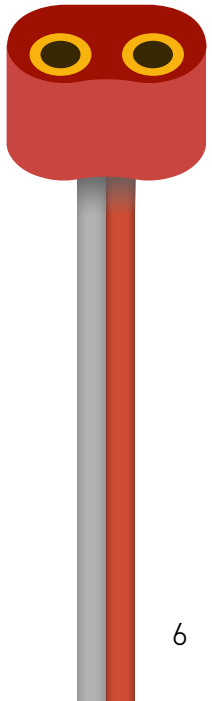
The battery system is modular to accommodate various prosthesis setups. Up to four FlexCells can be combined for a maximum capacity of 2200 mAh using FlexCells or 1320 mAh for FlexCell Minis.

OUTPUTS

FlexCell is compatible with most terminal devices.

FlexCell uses the 2-Pin Kidney-style output connector and has been tested with several prosthetic terminal devices such as hands, wrists, and elbow units. However, always confirm that your terminal device is compatible with FlexCell's specifications. If you have any questions regarding compatibility, please contact Infinite Biomedical Technologies.

The FlexCell system was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill mountain biking) or extreme sports (free climbing, paragliding, etc.). Furthermore the FlexCell system should not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.



2 Specifications

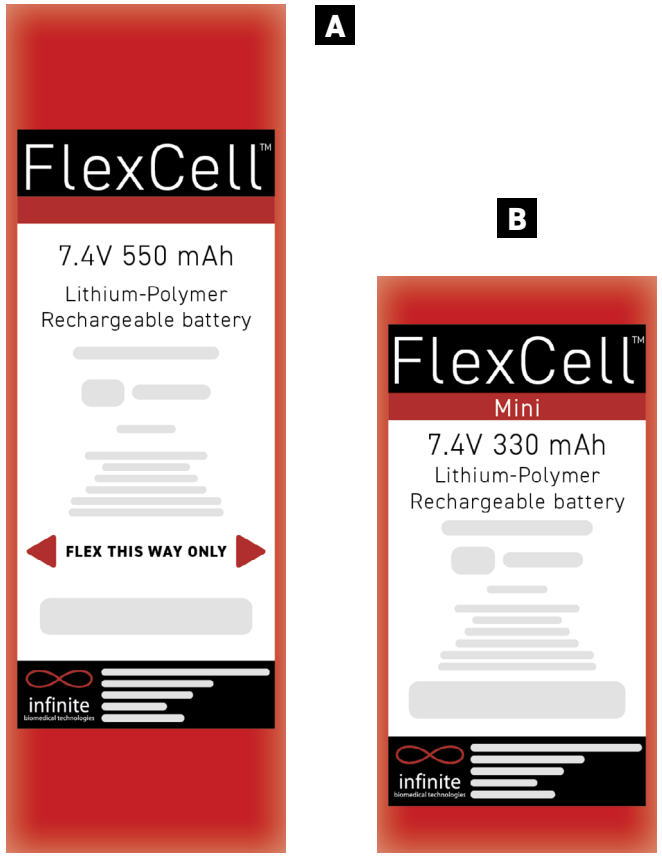
Temperature range (use)	0°C to +49°C (32°F to 120°F)
Temperature range (transport and storage)	0°C to +49°C (32°F to 120°F)
Humidity range (use)	0% to 90%
Humidity range (storage and transport)	0% to 95%
Dimensions Standard	4.9" X 1.57" X 0.08"
Dimensions Mini	3.25" X 1.57" X 0.08"
Voltage output	7.4V DC
Current output	Up to 7A (Maximum) 5A (Continuous)
Capacity (Standard/Mini)	550 mAh / 330 mAh
Expected service life	500 charges / 2 years
Weight (1x Standard/1x Mini)	31g / 17g

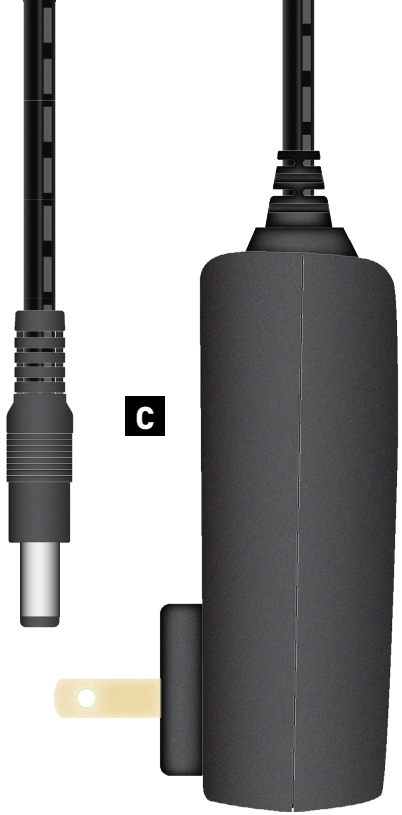
3 Installation

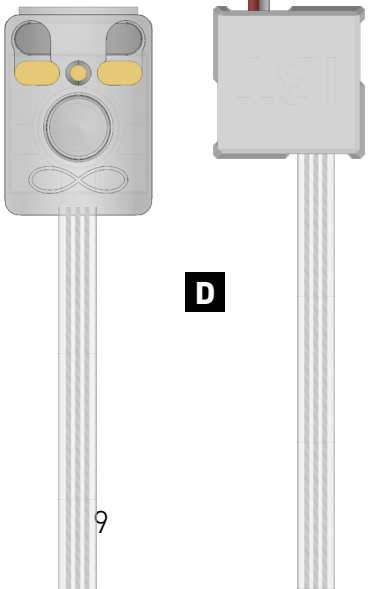
BEFORE YOU BEGIN

Included in the package:

(A) FlexCell battery
(B) FlexCell Mini battery (if applicable)
(C) Wall adapter
(D) Charging port
(E) 2 flanges for charging port
(F) Charger adapter

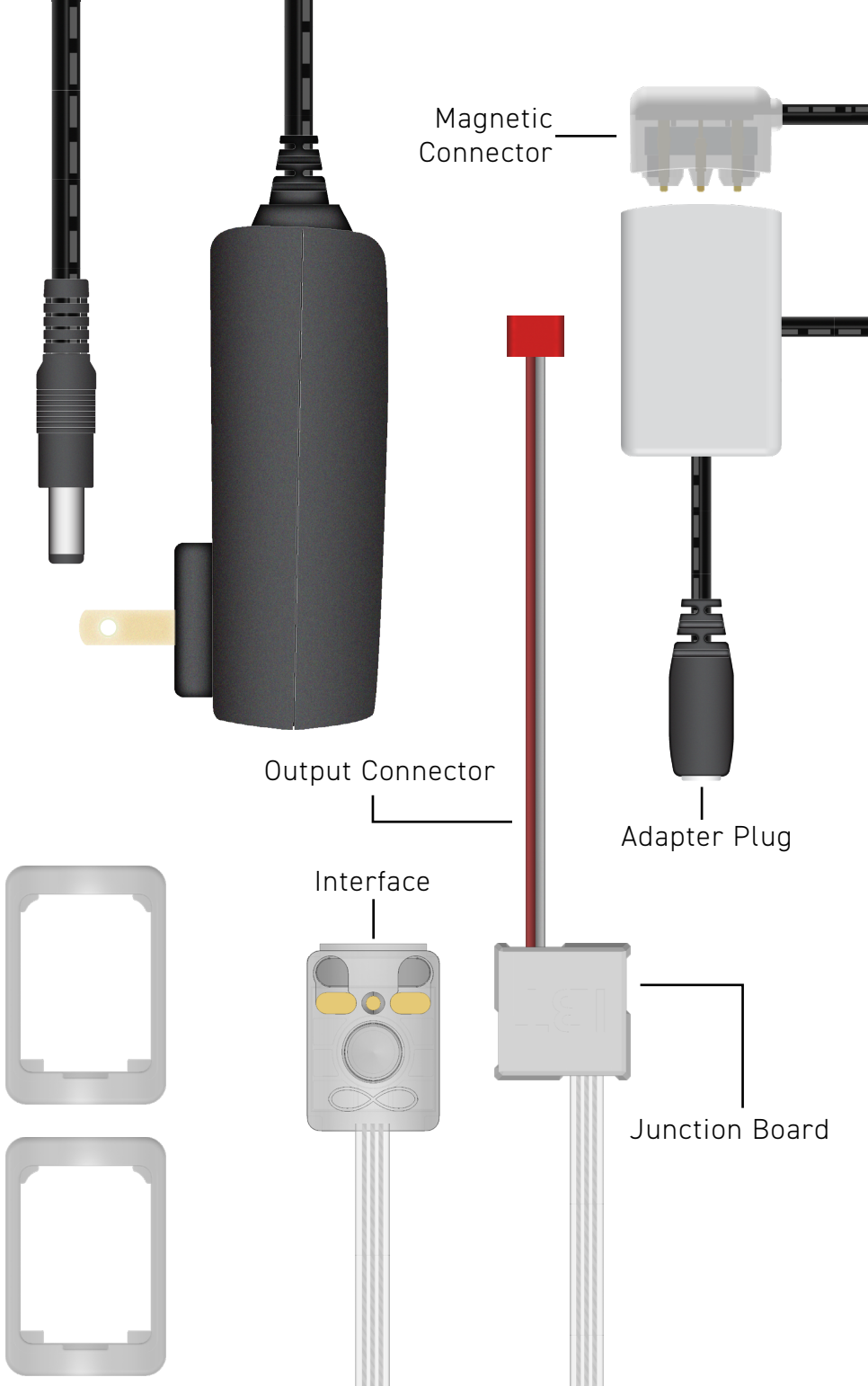




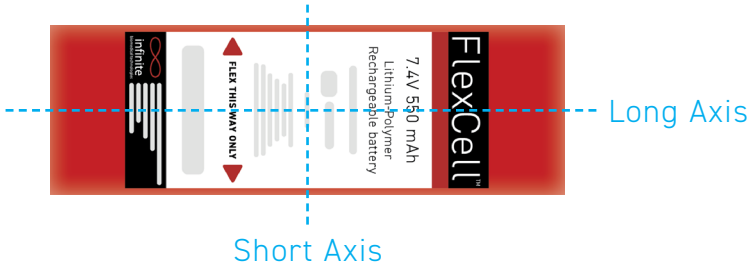


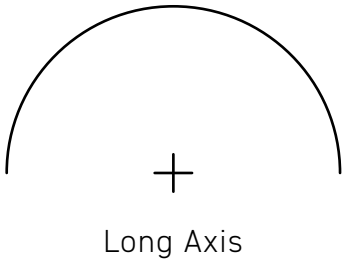
COMPONENTS


Battery Connector
FlexCell™
7.4V 550 mAh
Lithium-Polymer
Rechargeable battery
FLEX THIS WAY ONLY
infinite
biomedical technologies
FlexCell™
Mini
7.4V 330 mAh
Lithium-Polymer
Rechargeable battery
infinite
biomedical technologies


Magnetic
Connector
Output Connector
Adapter Plug
Interface
Junction Board

BEND RADIUS





FOR FLEXCELL
AND FLEXCELL MINI

R=0.875 in

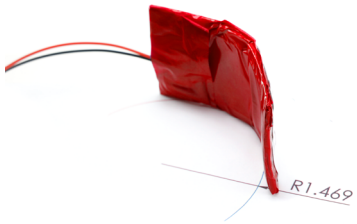
Pictured above is the to-scale maximum bend radius for the long axis of a FlexCell battery. The maximum bend curvature of the FlexCell cannot exceed the curvature depicted above.

550 mAh FLEXCELL ONLY

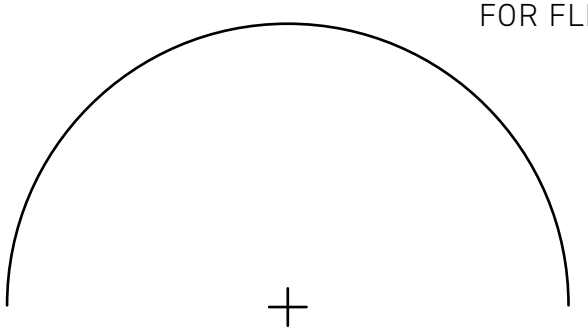
The FlexCell 550 mAh battery is not intended to bend around the short axis; doing so can damage the battery and void the warranty. Bend 550 mAh batteries around the long axis only.

Long Axis Example

Short Axis Example



FOR FLEXCELL MINI ONLY

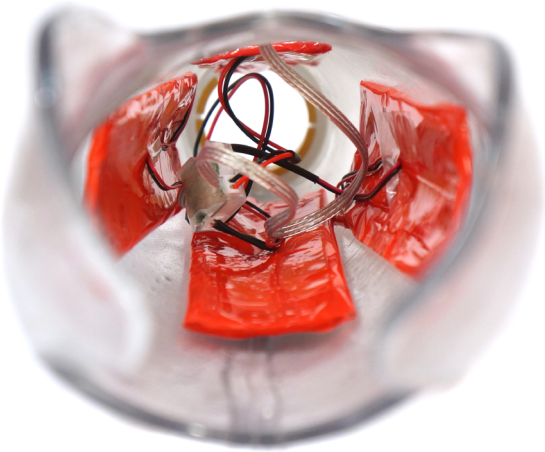


R=1.469 in

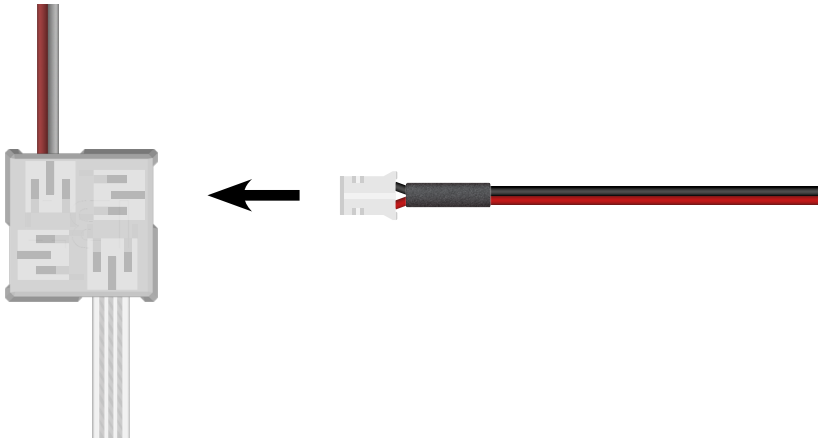
Pictured above is the to-scale maximum bend radius for the short axis of a FlexCell Mini battery. The maximum bend curvature of the FlexCell Mini cannot exceed the curvature depicted above.

HOW TO INSTALL FLEXCELL

If the charging port will be mounted on the prosthesis surface, place the provided flange in the desired location when molding the shell to create an accurate opening.



Place the FlexCell batteries anywhere within the prosthesis shell, taking care to ensure the batteries are not compressed and will never be in contact with the user's skin. Adhesives can be used to secure the batteries to the shell's inner surface.

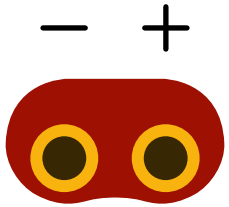


Slip the junction box into the prosthesis and connect each battery to the junction box on the controller. The connectors are designed to plug in only one way. Check the orientation if it does not plug in easily.

Only use FlexCell batteries with the FlexCell charging port and junction box.

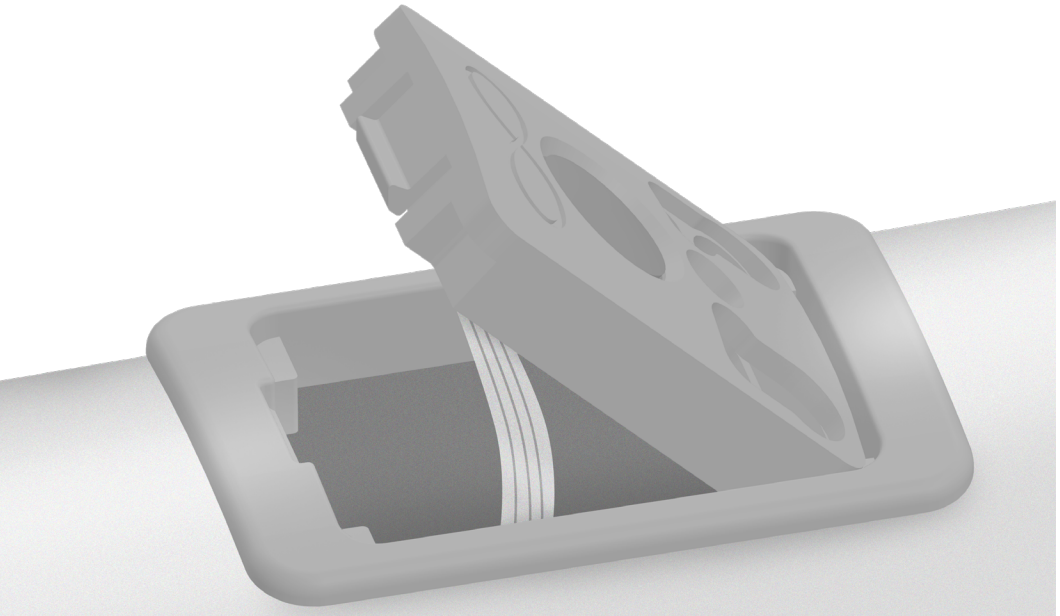
4 Using FlexCell

Connect the output connector to the terminal device. Pay close attention to the polarity of the connector depicted below.



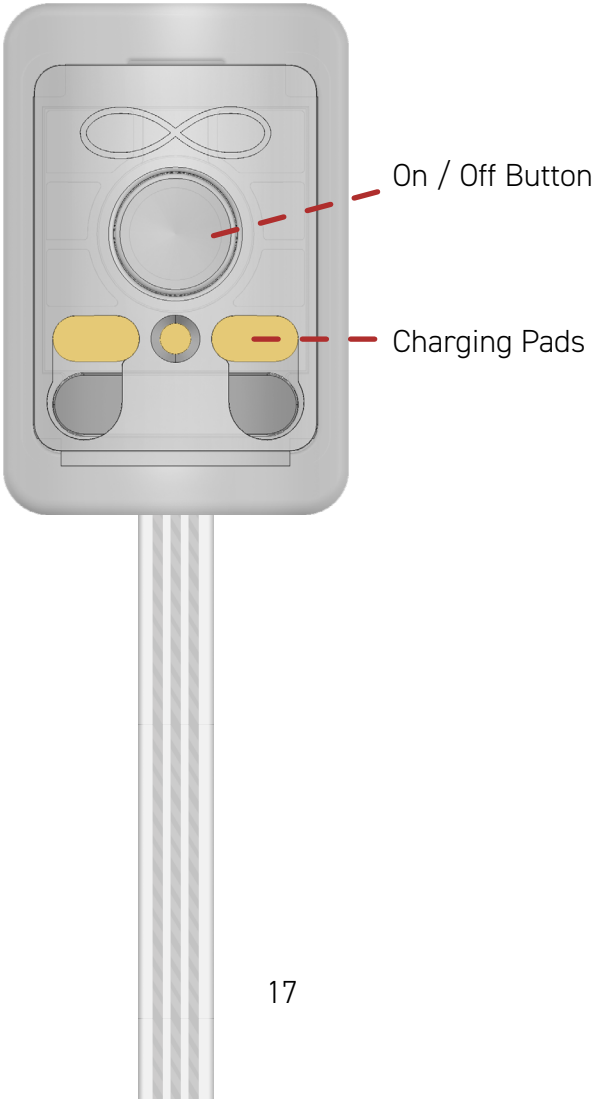
2-Pin Kidney-style connector

Insert the charging port into the flange. It is designed to only insert one way and should snap in easily. Check the orientation if it does not insert easily.



TURNING ON/OFF

Charging Port Interface



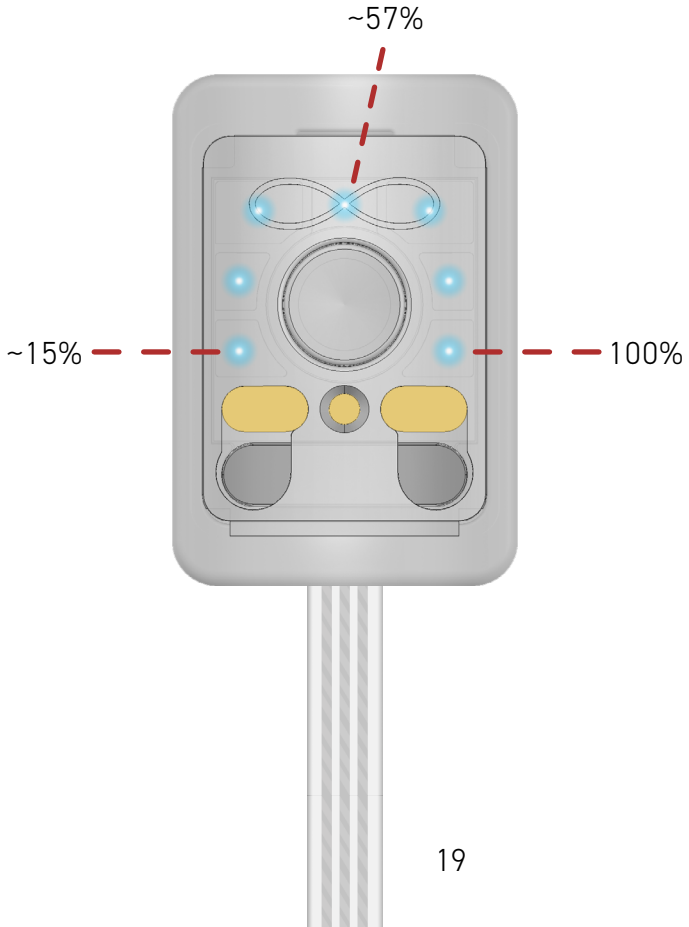
How to turn on FlexCell

To turn on Flexcell, press and hold the controller button for 3 seconds. The seven LEDs will illuminate around the button in a clockwise direction and flash. To turn off FlexCell, press and hold the Control Unit button for 3 seconds. The seven LEDs will illuminate around the button in a counter-clockwise direction.

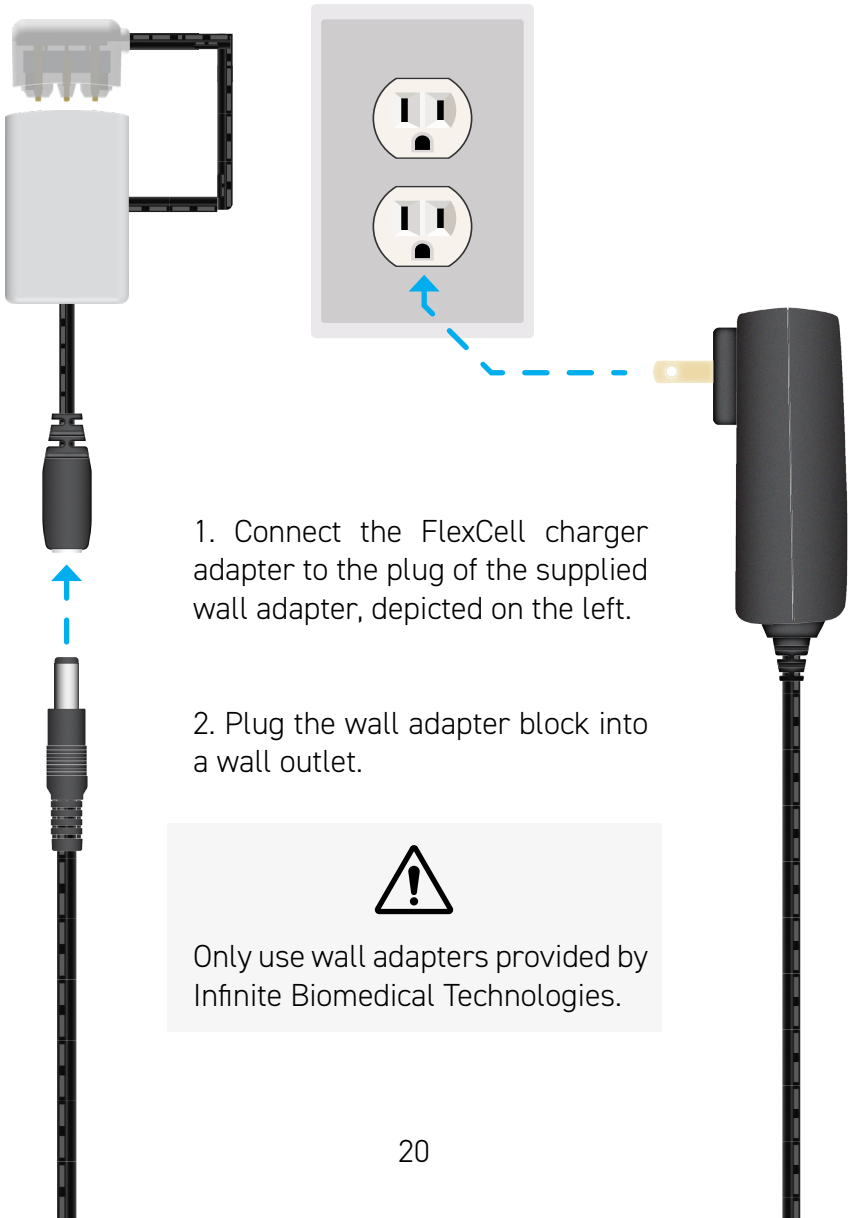
CHECKING BATTERY CHARGE

Press the charging port button to check the battery charge level. The number of lights that turn on (out of seven) provide an indication of capacity. The LEDs will blink when the system is turned off.

Note: Wait 20 seconds after plugging in the batteries or removing the charger before checking remaining capacity.



CHARGING THE BATTERIES



1. Connect the FlexCell charger adapter to the plug of the supplied wall adapter, depicted on the left.

2. Plug the wall adapter block into a wall outlet.

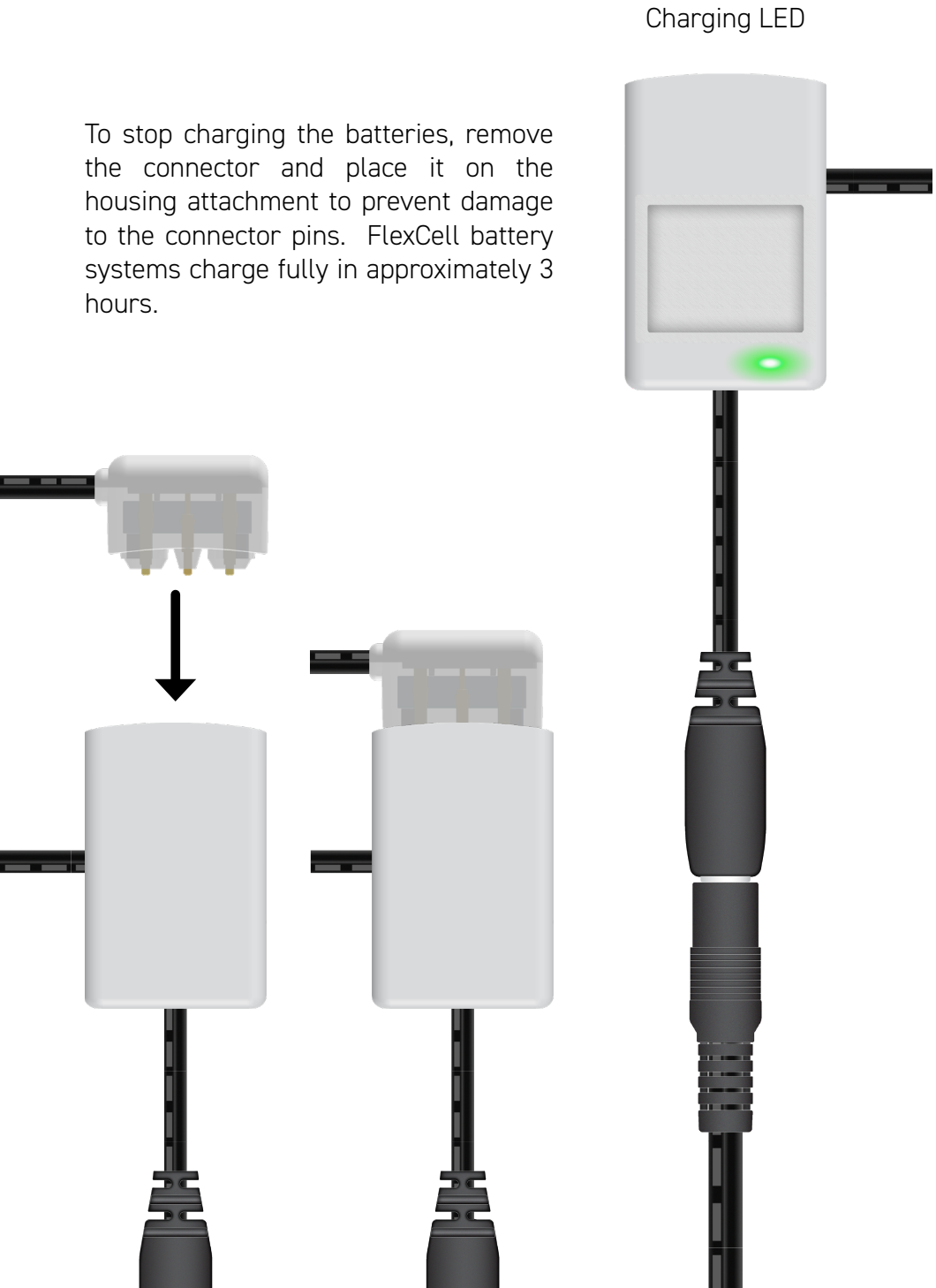
⚠

Only use wall adapters provided by Infinite Biomedical Technologies.

To charge the batteries, place the magnetic connector over the charging port's charging pads. The two magnets on the magnetic connector align with the steel bar on the charging port. The magnetic connector will snap in place.

A green LED will illuminate in the charger body when the batteries are charging. The green light will disappear when the batteries are done charging.

To stop charging the batteries, remove the connector and place it on the housing attachment to prevent damage to the connector pins. FlexCell battery systems charge fully in approximately 3 hours.



5 Maintaining FlexCell

PREVENTATIVE INSPECTION

All FlexCell battery systems undergo extensive quality assurance inspections upon receipt.

No additional inspection is required or advised.

SERVICE AND CLEANING

Perform a visual inspection of each battery and all wiring every few months. Make sure no connectors or wires are broken.

If batteries become inflated or excessively hot, discontinue use immediately and contact Infinite Biomedical Technologies.

Use a dry cloth to clean FlexCell components as necessary. The metal contacts on the charging port should be cleared of any debris build-up using a cotton swab or other non-metallic object such as a toothpick.

Do not attempt to repair or service FlexCell. Return components to Infinite Biomedical Technologies for all repair servicing.

Do not allow children to replace batteries without adult supervision.

REPAIRS, RETURNS, AND WARRANTY

Please contact IBT at support@i-biomed.com regarding repairs and returns. The FlexCell batteries, Charging Port, and Wall Charger come with a 1-year manufacturer's defect warranty. Details of the warranty are enclosed separately.

6 Safety and Warnings

Liquid damage warning: FlexCell is **not** designed to be waterproof. Do not submerge or spill liquid on or into the prosthesis as it will likely cause a malfunction in FlexCell. If the prosthesis will be worn in wet environments, ensure that FlexCell is sufficiently protected from the external environment.

Deformation warning: FlexCells should not be excessively bent. Excessive bending can damage the batteries. FlexCell 550 mAh should only bend along the long axis. Refer to the bend radius guide on page 12 and 13.

Compression warning: FlexCells should not be exposed to constant, large, instantaneous, or repeated compression. Doing so will damage the internal chemistry of the battery.

Modification warning: Any modification to FlexCell can pose a safety risk to the patient and will void the warranty. Do not unwrap the red covering on the batteries.

Charging warning: Do not wear prosthesis while charging batteries. **Only use chargers provided by Infinite Biomedical Technologies.**

Heat warning: Do not expose FlexCell to a heat source such as a fire, even if FlexCell is within the prosthesis. Do not leave FlexCell in a high-temperature environment (e.g. under direct sunlight or in a closed vehicle during hot weather)

Altitude warning: FlexCell may not meet its rated capacity when exposed to environments of extreme atmospheric pressure.

Malfunction warning: If a FlexCell battery begins to give off an odor, generates heat, becomes discolored, or in any way appears abnormal during use, recharging or storage, immediately remove the prosthesis and battery (contact prosthesist for battery removal), store the battery in a contained vessel and contact Infinite Biomedical Technologies.

Please note that portable and mobile RF communications equipment can affect FlexCell.

Disposal warning: Do not dispose of FlexCell in fire or heat. FlexCell should not be thrown away with common household garbage. Dispose of FlexCell by either returning the unit to Infinite Biomedical Technologies or at an official electronics diposal site.

INCIDENT REPORTING

Any serious incident needs to be reported to Infinite Biomedical Technologies and to the competent authority of the EU member state in which you and that patient are established.

IBT can be reached at:

Infinite Biomedical Technologies, LLC.
8 Market Place, Suite 500
Baltimore, MD 21202, USA
Phone: +1 (443) 451-7175
E-mail: info@i-biomed.com
Website: www.i-biomed.com

Contact information for competent authorities can be found at:
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

7 Regulatory Info

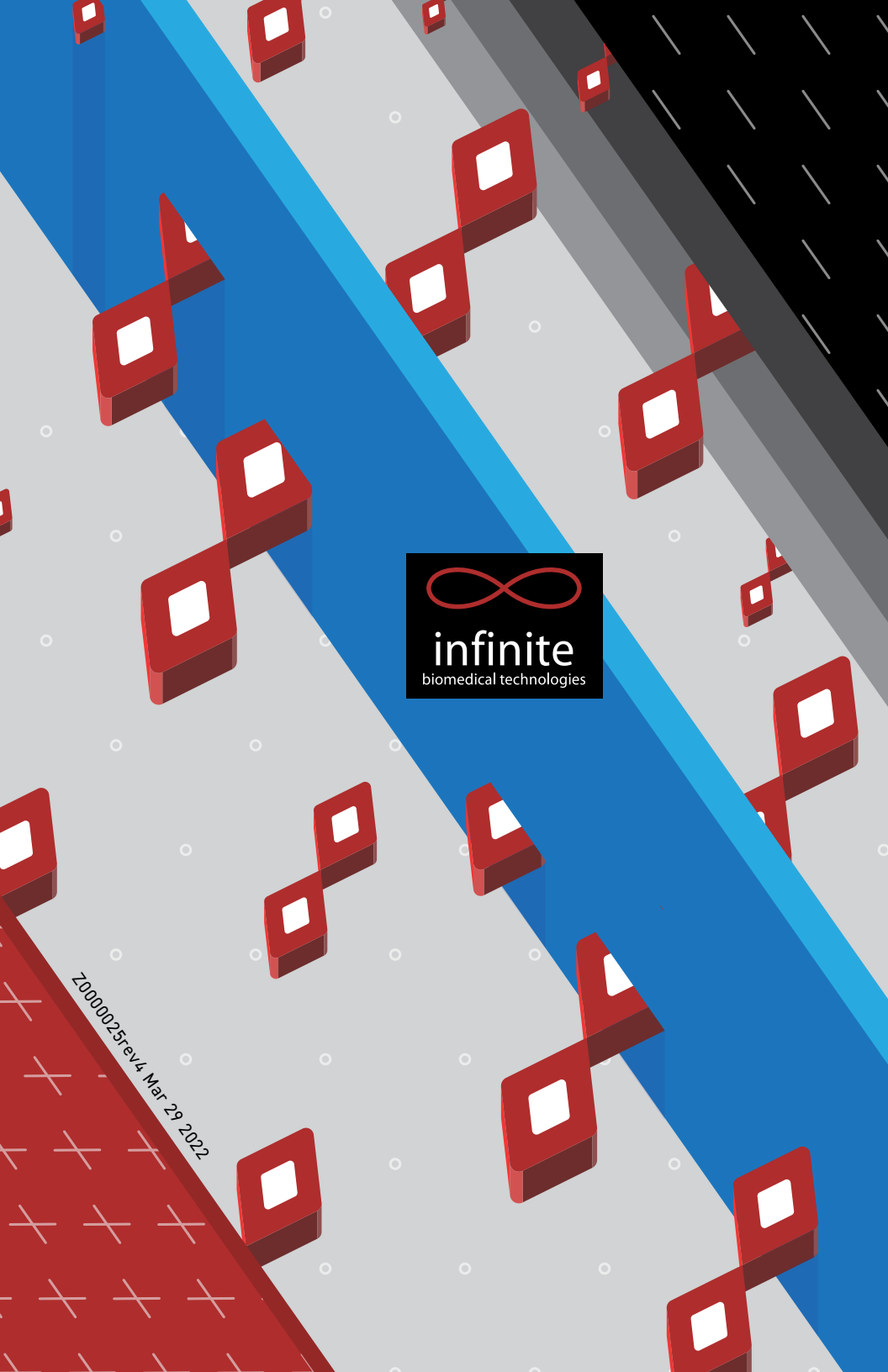
This product has been tested and verified to ensure that there are no issues or concerns regarding reciprocal interference. This includes EMI, EMC and RF.

This product has been certified and tested by 3rd party testing facilities to thefollowing standards:

IEC 60601-1, 3rd Edition
IEC 60601-1-2, 3rd and 4th Edition
IEC 60601-1-11, 1st Edition
IEC 61000

Also compliant as per CISPR 11:2015

NOTES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