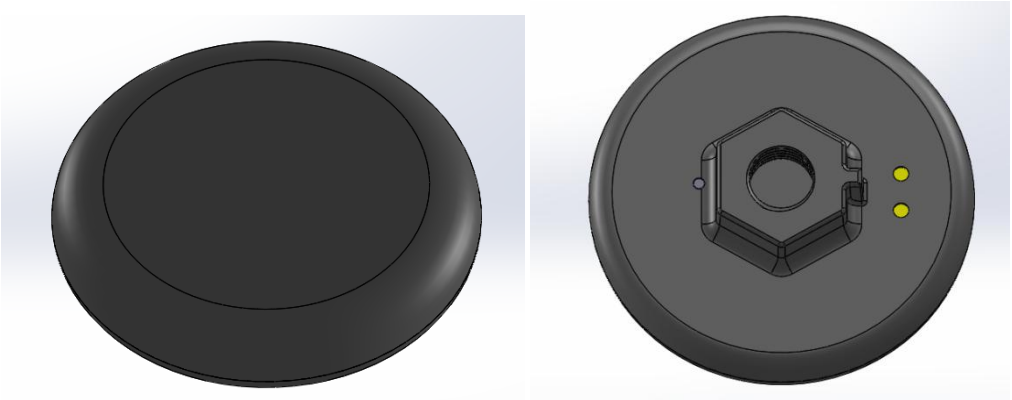
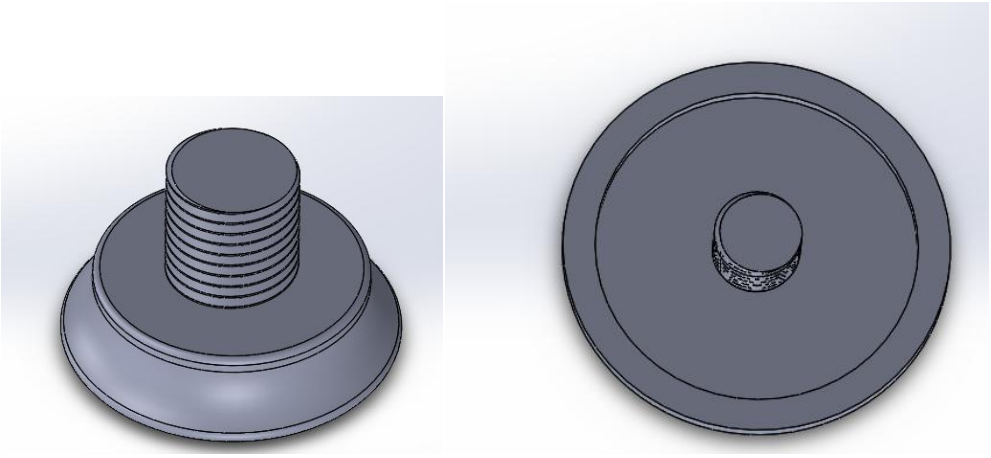
ROMBOT

PATIENT HANDBOOK





Contents

1 INTRODUCTION..... 3

2 INTENDED USE 3

3 EXPLANATION OF SYMBOLS 3

4 SAFETY INFORMATION..... 4

4.1 WARNINGS & CAUTIONS 4

5 ROMBOT..... 5

5.1 Fitting instructions..... 5

5.2 Application download; Device pairing; set up..... 6

5.3 Additional guidelines..... 7

1 INTRODUCTION

The OG Yili ROMBOT is a modular devised used for monitoring and analysing the characteristics of motion of the knee or other extremities. It communicates with an application interface and provides the user or medical professional with relevant feedback regarding the effected member and joint.
This device can be fitted either to Post Operative ROM brace or Lollipop soft garments.

 Read this User Manual carefully before using the device. Pay attention to the Safety Information. If any problems occur with the use of this product, immediately contact your medical professional.

Application

This product should be attached to a Post Operative ROM brace or a Lollipop soft garment, the module should be attached on the pivot point of the selected device and should be fully secure with either the provided thumb screw or backing cap. Locator tab ensures correct orientation of device, but ensure that selected body member has been specified in the app for analysis.

2 INTENDED USE

The ROMBOT is an externally applied orthopaedic apparatus intended to assist in the monitoring of the patient after injury; during recovery after surgery or for general well being. It is intended to supplement and assist analysis by a medical professional but is not intended to replace their input.

3 EXPLANATION OF SYMBOLS

The following symbols are used in this user manual, on the device packaging, or on the device or accessory labelling.

Reference number; part number

Lot number


Manufacturing date


Manufacturer name and address


Follow instructions for use


CE Marking

4 SAFETY INFORMATION

4.1 WARNINGS & CAUTIONS

Carefully read fitting instructions and warnings prior to use. To ensure proper performance of the device, follow all instructions. Failure to properly position the device will compromise performance and lead to inaccurate results.

This device will not prevent or reduce all injuries. Proper rehabilitation and activity modification are also an essential part of a safe treatment program. Consult your licensed health care professional regarding safe and appropriate activity level while wearing this device; the results should be used to supplement the input from your medical practitioner.

For single patient use only.

The ROMBOT is to be used for monitoring characteristics of motion and provide valuable feedback via the app, although one should still refer to a medical professional in order to ensure suggested treatments are safe for the individuals particular case.

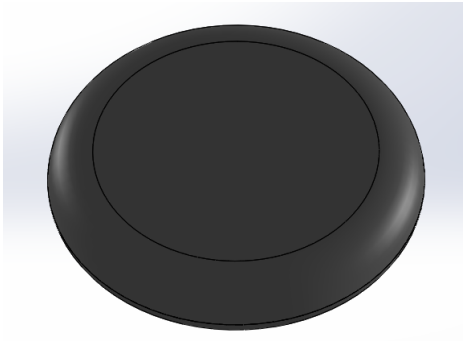
Materials of the unit may become flammable or combustible if exposed to a source of ignition.

Do not use OG Yili ROMBOT as a toy.
This product contains small components, keep out of reach of children.

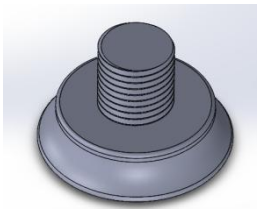
If pain is severe, stop treatment immediately. Failure to stop treatment could result in tissue damage and could compromise the surgical repair.

5 ROMBOT

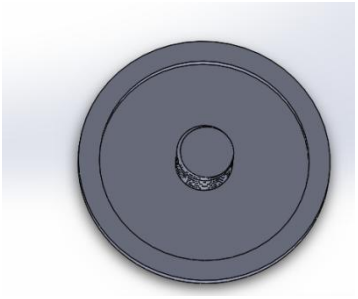
5.1 Fitting instructions for ROMBOT



ROMBOT



Thumb screw



Backing plate

5.1.1) Remove ROMBOT thumb screw or back plate by turning anti clockwise

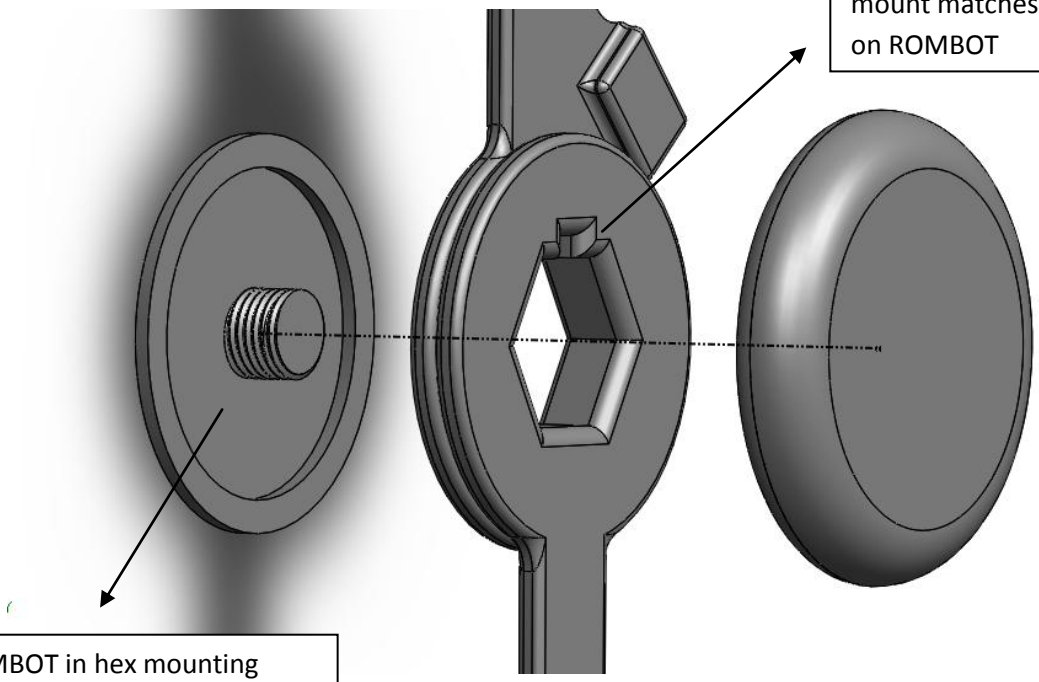
5.1.2) Position ROMBOT in the hexagonal mount of pivot point of selected device, taking note of the position of the locator notch.

5.1.3) Secure ROMBOT by attaching thumb screw or backing plate from the back of the pivot ; thumb screw or backing plate is tightened by rotating clockwise until ROMBOT is seated securely

5.1.4) Pair ROMBOT with app

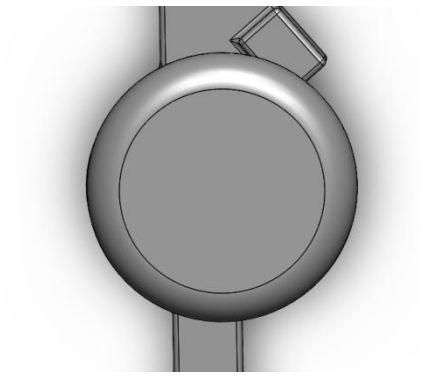
5.1.5) Checklist to ensure correct fit:

- ROMBOT positioned on the outside face of effected member, facing outwards
- ROMBOT is secure, locator fits in notch
- Attachment screw is secure
- Device is connected to ROMBOT
- Correct member and side is specified in app

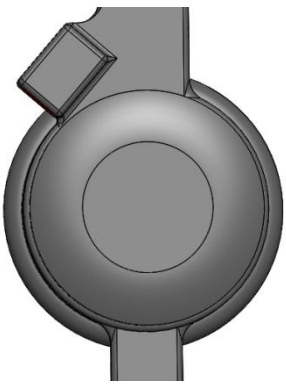


Ensure locator point on mount matches locator on ROMBOT

Place ROMBOT in hex mounting point and tighten back plate clockwise



ROMBOT correctly fitted to lollipop; front view



ROMBOT correctly fitted to lollipop; Back view

5.2 Application download; Device Set up

5.2.1 Application download:

- Scan QR code on box
- Follow link to app store (Apple) or ROMBOT.COM (Android)
- Select the download link
- Grant permission (Apple only):
  Settings → General → Device management → Joint Chinese Ltd →
  ROMBOT → Trust

5.2.2 Device set up:

Sign in:

- Provide active email address
- Select password
- Fill in personal data (Gender; age; weigh etc)

Device pairing:

- Turn on device Bluetooth
- Select setting (top right, app home screen)→ Notifications → Pair ROMBOT → Set up and discover → Device selection (e.g.: right knee) → Install device (Searching)→ Select unique ID code→ Pair

Base line data:

- Settings → Notifications → Complete profile → Select injury → Specify Injury → Prior surgery→ Type of surgery → Date of surgery

5.3 Additional guidelines

General guidelines:

- ensure brace/ lollipop in centred on side of leg
- Check to see that Brace/lollipop returns to a straight position (if leg condition allows)
- On initial application, test ROMBOT with interactive angle displace to ensure correct function and reference to leg position

Specific guidelines (as indicated by health care practitioner):

Physician:_____

Name:_____

Phone number:_____

Follow up appointment:_____

Warranty and after sales services

All returned units to the factory should include:

1. Written statement containing the following information:
    - Unite model number
    - Unit serial number
    - Contact person with phone and email
    - Billing address (for out of warranty repair)
    - Shipping address (where to ship unit after repair)
    - Detailed description of problems or symptoms
    - RA Number – Obtain from factory
2. Copy of the original invoice issued during purchase of the unit
3. Ship unit to the factory in the original container with all accessories and information as required in item 1 above

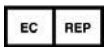
OgYili ("Company") warrants that the Totus post-op ROM unit ("product") is free of defects in material and workmanship. This warranty shall remain in effect for one year (12 months) from the date of the original consumer purchase. If this product fails to function during the one year warranty period due to a defect in material or workmanship, Company or the selling dealer will repair or replace this Product without charge within a period of thirty (30) days from the date on which the Product is returned to Company or dealer.

Company shall not be liable in any event for incidental or consequential damages.

Some companies only cover products if the user decides to participate in a warranty program. So we would have them register their product online. Or we can just give warranty to everyone. Also how long would we like to offer warranty for?

Standards Compliance

- Complies with essential requirements of CE directive 93/42/CEE applicable to class I medical equipment



For medical devices, it is **compulsory**, under the **Medical Devices Directive** which became effective on 14/Jun/1998, that the manufacturer designate an **Authorized Representative** which has to be **located in European Union member states** to produce Technical Documentation (or sometimes called Technical File) in a timely fashion when called upon to do so by the Surveillance Authorities.

In order for us to use the EC REP marking we must have an authorized representative – I will look into the process for this

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.