

Motiva Flora[®] Port Locator

Directions for Use



DIRECTIONS FOR USE MOTIVA FLORA® PORT LOCATOR

Establishment Labs S.A.

CAUTION:

- Only health professionals with qualified training and licensed by the corresponding national boards should use it. The use of this product by unqualified practitioners may result in inferior aesthetic outcomes and serious adverse health effects.
- Federal (USA) law restricts the sale of this device to licensed healthcare practitioners.

INTRODUCTION

This document provides an overview of essential information about the Motiva Flora® Port Locator, including the device description, indications for use, contraindications, warnings, precautions, relevant topics, returned goods policy, and warranty.

RELEVANT TOPICS THAT MUST BE DISCUSSED WITH THE PATIENT

Doctors and health professionals must thoroughly read and understand this document's contents and ensure that all patient questions or concerns have been resolved prior to using the device.

INTENDED USE /INDICATIONS FOR USE

The Motiva Flora® Port Locator (Figure 1) interacts exclusively with the Motiva Flora® Tissue Expander product family to easily locate the breast tissue expander's integrated port and enable accurate injection filling.

WARNING: Please read the user manual (this document) carefully before using the device. Failing to read the instructions can cause adverse situations for the patient.

INTENDED PATIENTS

Motiva Flora® Port Locator is intended to be used in patients who require a staged tissue expander-based breast reconstruction with Motiva Flora® Tissue Expander product family.



Figure 1: Motiva Flora® Port Locator

PRECAUTIONS

The Motiva Flora® Port Locator should only be used as indicated in this document.

- Before use, read the instructions for use carefully.
- Failure to follow the safety instructions may damage the device and/or cause an injury to the patient.
- Check Motiva Flora® Port Locator for damage before use.
- DO NOT expose the device to extreme temperatures (below 0 °C or above 39 °C), direct sunlight, or extreme humidity (below 35 % or above 75 %).
- Hospitals and medical clinics are suitable environments to use the Motiva Flora® Port Locator, except for areas near high electromagnetic (EM) disturbances, other active radiofrequency (RF) devices, or RF shielded rooms.
- Portable RF communication equipment (including peripherals such as antenna, cables, and external antennas) should not be used closer than 1 meter (39 inches) to any part of the Motiva Flora® Port Locator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals; if it is used in a residential environment, this equipment might not

offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- DO NOT modify the device in any way.
- DO NOT use abrasive cleaners or solvents on the device.
- DO NOT use the device while it is being charged.

CONTRAINDICATIONS

- DO NOT use on patients who have implanted devices that could be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices).

DEVICE DESCRIPTION

The Motiva Flora® Port Locator is a non-invasive electronic medical device that interacts exclusively with the Motiva Flora® Tissue Expander product family to locate the injection port within the tissue expander. Motiva Flora® Port Locator uses a radiofrequency identification (RFID) wireless system comprising two components: tags and readers. The Motiva Flora® Port Locator (reader) has an antenna that emits radio waves and receives signals back from the RFID tag.

The air wound coil (a passive RFID tag) is a component that is located inside the needle stop of the Motiva Flora® Tissue Expander product family and uses radio waves to communicate its location to the Motiva® Port Locator. This wireless system locates the center of the injection port. The user interface of the Motiva Flora® Port Locator includes LED lights to guide the user during the process. (Figure 2)

Basic UDI-DI: 7445161PortlocatorUY

COMPONENTS

The following components are included inside the Motiva Flora® Port Locator package:

- Port Locator
- USB cable
- Directions for Use
- Motiva Flora® Port Locator Quick Reference Guide

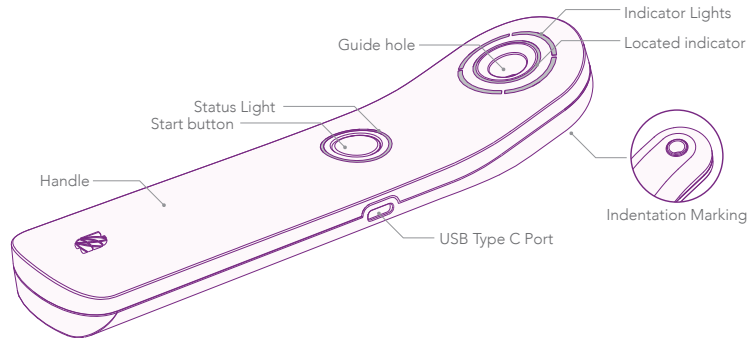


Figure 2: Port Locator Parts

TECHNICAL SPECIFICATION

Component	Description
Software	Version 1.5.2
Battery	Rechargeable Lithium Ion Battery Weight: 20.5g Dimensions : 38.6mm x 59mm x 4.5mm Output: 1250mAh Nominal voltage: 3.7 V
Case	ABS material Overall dimensions: Height: 18-23mm, Width: 49.9mm, Depth: 201.44mm
Indicators	1 Illuminated button "start" 1 illuminated circle white "location indicators" 1 Illuminated circle green "located"
USB Cable	Type C-USB Port

Wireless technical specifications	
Complies with:	IEC 60601-1, IEC 60601-1-2, AIM 7351731, FCC 47 CFR Part 15 Subparts B and C
Resonance frequency:	135.35 kHz
Maximum effective radiated power:	87 dBµV/m at 3 m
Modulation:	OOK/ASK
Operating range:	0-55 mm (2.165 in) from injection port

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. Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment. This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant

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to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

WARNING: There are no user-serviceable parts in the device.

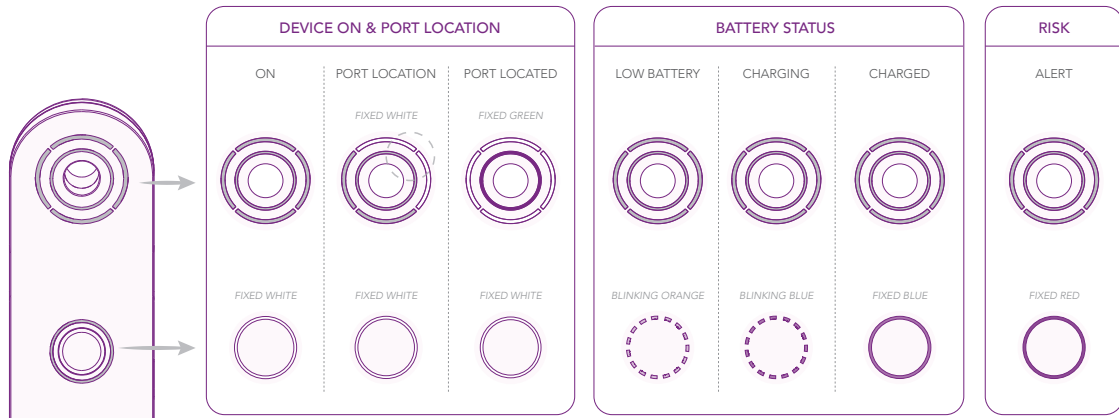


Figure 3: Battery status indicators

BATTERY

Motiva Flora® Port Locator is equipped with a Lithium-Ion polymer rechargeable battery.

Battery Status Indicator (Figure 3)

- Solid white: Ready to be used
- Blinking Orange: Battery needs to be charged
- Blinking Blue: Charging in process
- Solid Blue: The device is fully charged

WARNING: Solid Red light indicates detection of interference and/or fault condition; please do not try to use the device.

BATTERY RECHARGING INSTRUCTIONS:

The device's battery has an operating voltage of 3.7 V and can be easily recharged with a USB cable: Motiva Flora® Port Locator includes an IEEE 1394 Cable USB for Type C USB Port.

NOTE: Wall charger must be approved IEC 60950 Class II power supply. Output voltage DC 5V@1A. Input voltage AC 100V/240V and Input voltage frequency 50Hz/60Hz depends on the country's standard.

WARNING:

- The device must be used exclusively with the Motiva Flora® Tissue Expander product family.
- The device must be connected to an appropriate power source.
- The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The device must not be used in a potentially explosive environment. Do not turn on the Motiva Flora® Port Locator in potentially explosive environments, such as gas stations. Motiva Flora® Port Locator usage is restricted in areas with fuel, chemical plants, or where blasting operations are in progress.
- DO NOT use the device while it is being charged.
- NEVER use the device when the status light is blinking orange.

ELECTROMAGNETIC SAFETY TESTING

Test	Power input voltage	Line frequency
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11.	5 VDC	N/A
ELECTROSTATIC DISCHARGE IMMUNITY IEC 61000-4-2	Motiva Flora® Port Locator shall be able to withstand ± 8 kV air discharge and ± 8 kV contact discharge without damage.	N/A

Test	Power input voltage	Line frequency
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	A field of 10 V/m modulated by a 1 kHz 80% AM modulation over the frequency range of 90 kHz to 80000 kHz.	N/A

IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted RF DISTURBANCE IMMUNITY) – a.c. mains IEC 61000-4-6	5V rms, 90 KHz to 80 MHz with an 80% AM with a 1 KHz sine wave AC & DC power 5V rms sig/control >3 m, 90 KHz to 80 MHz with an 80% AM with a 1 KHz sine wave.	N/A
IMMUNITY to conducted DISTURBANCES induced by RF fields (conducted disturbance immunity) – SIP/ SOP PORTS IEC 61000-4-6	5V rms, 90 KHz to 80 MHz with an 80% AM with a 1 KHz sine wave AC & DC power 5V rms sig/control >3 m, 90 KHz to 80 MHz with an 80% AM with a 1 KHz sine wave.	N/A
Power frequency magnetic field IMMUNITY IEC 61000-4-8.	30 A/m at 60 Hz.	N/A

INSTRUCTIONS FOR USE

- “Motiva Flora® Port Locator Quick Reference Guide” is included inside the device’s box as a quick instructions reference guide to avoid errors during its use. Keep it handy for future reference.

- The Motiva Flora® Port Locator functionality is not affected when in the presence of devices like smartphones, tablets, laptops and Wifi node modules.
- Establishment Labs strongly recommends fully charging the battery before using the device for the first time.

NOTE:

- Motiva Flora® Port Locator can be safely used in the temperature range of 0 °C to 39 °C.
- Motiva Flora® Port Locator can be safely used in the relative humidity range of 35 % to 75 %.
- Motiva Flora® Port Locator can be safely used in the atmospheric pressure range of 70.0 kPa to 106.0 kPa.
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PRECAUTIONS: Read the instructions carefully before using the device. Failure to read the instructions may cause unnecessary risk to the patient.

WARNING:

- Having two Motiva® Port Locators within thirty centimeters (12 inches) of each other

may cause interference and affect the localization of the injection port.

- Motiva Flora® Port Locator's strength is affected by metallic materials, be careful to use Motiva® Port Locator at least 15 centimeters (6 inches) away from metallic surfaces.
- Not for use in an oxygen-rich environment and flammable anesthetics.

1. PRELIMINARY PRODUCT EXAMINATION

Verify outside the sterile field that the Motiva Flora® Port Locator's lights turn on when near the Tissue Expander. It is not necessary to open the packaging of the Tissue Expander to verify its functionality before implantation.

2. CLEANING THE DEVICE

Motiva Flora® Port Locator is a nonsterile device. Therefore, before reusing the locator for subsequent filling, it must be cleaned and disinfected using a lint-free cotton cloth and isopropyl alcohol. NEVER use abrasive products or solvents. (Figure 4)

WARNING:

DO NOT USE the Motiva Flora® Port Locator if it comes in contact with blood or mucous membranes. Users must disinfect per hospital procedures and discard the Port Locator.

3. TURNING ON THE DEVICE

Caution: To avoid interference, turn on the Motiva Flora® Port Locator 30 cm (12 inches) away from the Motiva Flora® Tissue Expander product family. A solid red light will turn on if you omit this indication. The device includes an ON button (Figure 5). A white light indicates that the Motiva Flora® Port Locator is on.

- Turn on the Port Locator by pressing the button and release once the white light ring is turned ON.

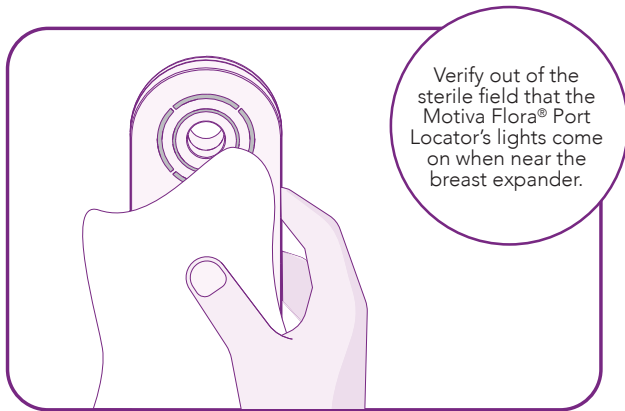


Figure 4: Cleaning and disinfecting the device.

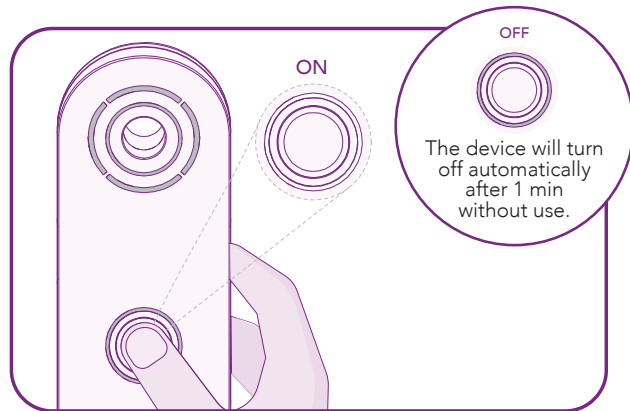


Figure 5: Power button.

4. LOCATING THE INJECTION PORT

- Place and move the device as close as possible to the surface of the breast to obtain the best results in locating the injection port.
- White lights will turn on guiding the location of the port. (Figure 7)

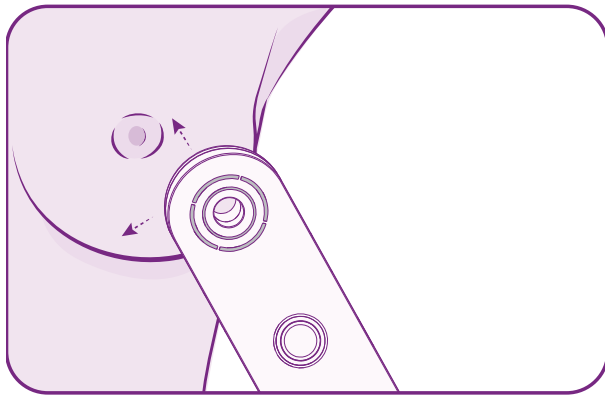


Figure 6: Scan port.

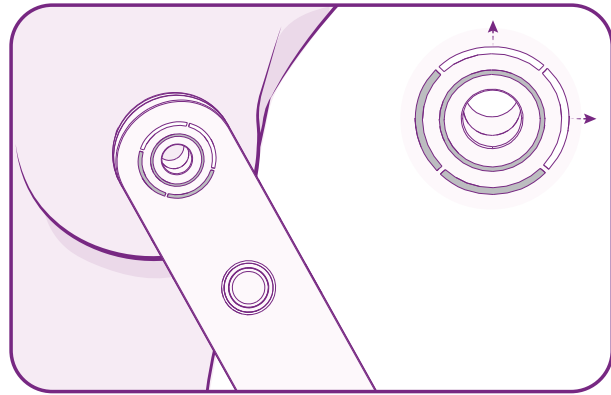


Figure 7: Locating injection port.

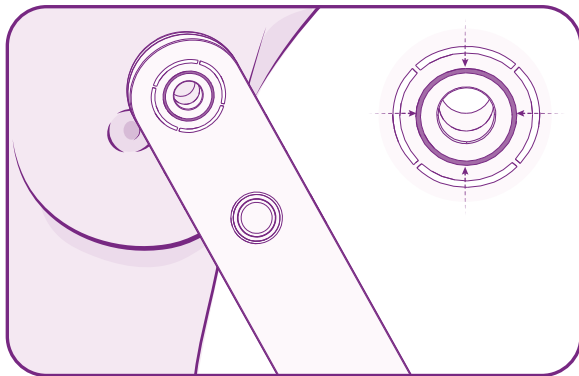


Figure 8: Injection port location.

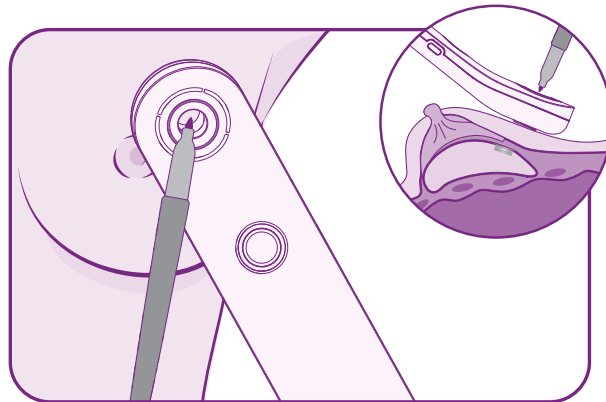


Figure 9: Marking injection point.

- Once the injection port is located, a green light ring will turn on. (Figure 8)

Marking:

- Hold the device steady and mark the location of the injection through the opening of the device with a surgical marker perpendicular to the breast skin and/or pressing down firmly on the device to create a temporary indentation on the skin where the port is located. (Figure 9)

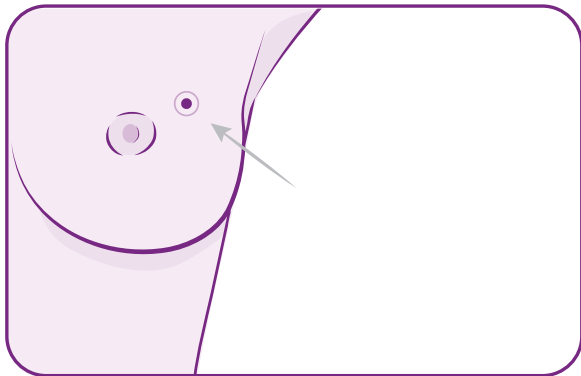


Figure 10: Injection point.

NOTE: Fill the tissue expander according to the Directions for Use for the Motiva Flora® Tissue Expander product family.

WARNING: If injections are made outside the injection port, leakage can occur.

STORAGE AND HANDLING CONDITIONS

Packaged units should be stored flat in a designated area within the hospital/clinic, protected from excessive temperature (below 0 °C or above 39 °C), light, and moisture (below 35 % or above 75 %). Keep it dry. Precautions should be made during transportation of the units to avoid excessive movement; the device can be broken or damaged if not handled carefully.

EXPECTED BENEFITS

Motiva Flora® Port Locator with RFID technology for locating the breast tissue expander's integrated port facilitates the potential benefit, of being compatible with imaging methods, and may increase the convenience of using Motiva Flora® Tissue Expander product family during clinical management without affecting the safety or effective tissue expansion performance.

The Motiva Flora® Tissue Expander product family needle stops are made of a plastic

component (PEEK Optima® LT1), which encloses the needle stop coil made of copper and a soldered RFID chip, nonmagnetic metals with low magnetic susceptibility. These non-ferromagnetic materials for the needle stop and an RFID-based port locator allow an implanted patient to undergo MRI under certain conditions (MR conditional).

INFORMATION ON LIFE EXPECTANCY

The expected service life of the Port Locator is 30 months upon receipt by the surgeon. Establishment Labs does not guarantee the device's functionality after its expected service life.

MAINTENANCE

Motiva Flora® Port Locator does not require any maintenance. The user should NEVER attempt to service or repair the device. In case the device stops working, please contact Establishment Labs through the website: www.motiva.health. To comply with the return and disposal of electrical and electronic equipment. Please send the Motiva Flora® Port Locator for disposal to:

Establishment Labs

Coyol Free Zone and Business Park Building
4th Street, Building B-15, Alajuela, 20113, Costa Rica.
Phone: +506 2434-2400
Email: customerservice@establishmentlabs.com
Website: www.motiva.health

NOTE: Do not dispose of the battery in fire. Battery disposal regulations vary on national, state/provincial, and local bases. Disposal must be conducted following the applicable regulations.

PRODUCT ORDERING

To order directly, or for product information, please contact your local Establishment Labs S.A. representative. In case there is no local representative contact:

Establishment Labs

Coyol Free Zone and Business Park Building
4th Street, Building B-15, Alajuela, 20113, Costa Rica.
Phone: +506 2434-2400
Website: www.motiva.health/support

REPORTING AND DEVICE RETURN EFFORTS

In the event of a Motiva Flora® Port Locator malfunction, the device must be returned to the local Establishment Labs representative. In case there is no local representative available, report directly to:

Establishment Labs S.A.

Coyol Free Zone and Business Park Building,
4th Street, Building B-15, Alajuela, 20113, Costa Rica
Phone: +506 2434-2400
Website: www.motiva.health/support/

NOTE: Any severe incident with Motiva Flora® Port Locator should be reported to Establishment Labs and the competent authority in which the patient is established, if applicable according to local regulations.

RETURNED GOODS POLICY

Product returns should be handled through the local Establishment Labs representative. In case there is no local representative available, report directly to:

Establishment Labs

Coyol Free Zone and Business Park Building
4th Street, Building B-15, Alajuela, 20113, Costa Rica.
Phone: +506 2434-2400
Website: www.motiva.health/support

All package seals must be intact for goods to be eligible for return. Returned products may be subject to a restocking fee. For more information, please contact the local Establishment Labs representative.

ESTABLISHMENT LABS WARRANTY

Establishment Labs warrants that this product is free of manufacturing defects at the time of its shipment. Establishment Labs shall not be responsible for any incidental or consequential loss, damage, or expenses directly or indirectly arising from the use of this product. If Establishment Labs determines the product was defective when shipped by the manufacturer, Establishment Labs' sole responsibility is to replace the product. Establishment Labs S.A assumes no further liability. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law, or otherwise, including, but not limited to, any implied warranties of merchantability, suitability for use or performance.

LEGAL MANUFACTURER**ESTABLISHMENT LABS S.A.**

Coyol Free Zone and Business Park Building
4th Street, Building B-15, Alajuela, Costa Rica.

Phone: +506 2434-2400

Email: customerservice@establishmentlabs.com

Website: www.motiva.health

EUROPEAN REPRESENTATIVE

Emergo Europe: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands.








EUROPEAN IMPORTER**EDC Motiva BVBA**

Nijverheidsstraat 96, Wommelgem

Antwerp, 2160 Belgium

Phone: +32 34324170

Symbols used in product labeling (including non-harmonized symbols)

Symbol	Meaning	Symbol	Meaning
 FCC ID: 2A9RPMFPL001	Federal Communications Commission register ID number	 E115143	MET Labs listing number: this means that the device has been evaluated for a limited range of hazards or suitability for use under limited or special conditions.
	Waste electrical and electronic equipment (WEEE)		Refer to the directions for use
	Conformité Européenne mark		Type B applied part: the backside of the device could be in touch with the patient.
IP X4	Protected against splashing water		Non-sterile

	Do not used if package is damaged		Keep dry
	Temperature limit		Humidity limitation
	Fragile, handle with care		Consult instructions for use
	Caution		Atmospheric pressure limitation
	Manufacturer		Medical Device
	Date of manufacture		Serial Number

	Unique Device Identifier		Quantity of accesories or medical devices included in the package.
	Catalogue number		Authorized representative in the European Community
	This way up		Keep away from sunlight
	Stacking limit by number		Importer
	Country of manufacture		UK conformity assessed

EN Hereby, Establishment Labs declares that the radio equipment type Motiva Flora® Port Locator MFPL-001 is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: / **BG** С настоящото Establishment Labs декларира, че радиооборудването тип локатор на порт Motiva Flora® MFPL-001 е в съответствие с Директива 2014/53/ЕС. Пълният текст на ЕС декларацията за съответствие е достъпен на следния интернет адрес: / **CS** Tímto společnost Establishment Labs prohlašuje, že typ rádiového zařízení lokátor portu Motiva Flora® MFPL-001 je v souladu se směrnicí 2014/53/EU. Úplné znění EU prohlášení o shodě je k dispozici na této internetové adrese: / **DA** Establishment Labs erklærer hermed, at radioudstyrstypen Motiva Flora® portfinder MFPL-001 er i overensstemmelse med direktiv 2014/53/EU. Den fuldstændige tekst for EU-overensstemmelseserklæringen findes på følgende internetadresse: / **NL** Hierbij verklaart Establishment Labs dat het type radioapparatuur Motiva Flora®-poortlokalisator MFPL-001 conform is met Richtlijn 2014/53/EU. De volledige tekst van de EU-conformiteitsverklaring kan worden geraadpleegd op het volgende internetadres: / **ET** Establishment Labs deklareerib käesolevaga, et raadioseadme tüüp Motiva Flora® Port Locator MFPL-001 vastab direktiivile 2014/53/EL. EL-i vastavusdeklaratsiooni täistekst on saadaval järgmisel internetiaadressil: / **GD** Dearbhaíonn Establishment Labs leis seo go bhfuil an cineál trealaimh raidió Motiva Flora® Port Locator MFPL-001 i gcomhréir le Treoir 2014/53/AE. Tá téacs iomlán an Dearbhaithe Comhréireachta AE le fáil ag an seoladh Idirlín seo a leanas: / **DE** Establishment Labs erklärt hiermit, dass die Funkanlage vom Typ Motiva Flora® Port Locator MFPL-001 die Richtlinie 2014/53/EU erfüllt. Der Gesamtwortlaut der EU-Konformitätserklärung ist unter folgender Internet-Adresse abrufbar: / **EL** Δια της παρούσας, η Establishment Labs δηλώνει ότι ο εντοπιστής θύρας Motiva Flora® τύπου ραδιοεξοπλισμού MFPL-001 συμμορφώνεται με την Οδηγία 2014/53/ΕΕ. Το πλήρες κείμενο της δήλωσης συμμόρφωσης της ΕΕ υπάρχει διαθέσιμο στην ακόλουθη διαδικτυακή διεύθυνση: / **ES** Por el presente, Establishment Labs declara que el localizador de puerto Motiva Flora® MFPL-001 es un tipo de dispositivo de radiofrecuencia que cumple la directiva 2014/53/UE. El texto íntegro de la declaración de conformidad de la UE se puede consultar en la siguiente dirección de Internet: / **FI** Establishment Labs ilmoittaa täten, että radiolaitetyypinen MFPL-001 Motiva Flora® Port Locator -paikannin on direktiivin 2014/53/EU mukainen. EU:n vaatimustenmukaisuusvakuutus on saatavilla kokonaisuudessaan seuraavasta osoitteesta: / **FR** Establishment Labs déclare par les présentes que le localisateur de port Motiva Flora® MFPL-001 est un appareil radio conforme à la directive européenne 2014/53/UE. Le texte de la déclaration de conformité UE peut être consulté dans son intégralité à l'adresse Internet suivante: / **HR** Tvrtka Establishment Labs izjavljuje da je radijska oprema lokatora porta tipa Motiva Flora® MFPL-001 u skladu s Direktivom 2014/53/EU. Puni tekst EU izjave o sukladnosti dostupan je na sljedećoj internetskoj adresi: / **HU** Az Establishment Labs kijelenti, hogy a Motiva Flora® portlokátor MFPL-001 elnevezésű rádiófrekvenciás berendezéstípus megfelel a 2014/53/EU irányelvnek. Az EU-s megfelelőségi nyilatkozat teljes szövege elérhető a következő internetes címen: / **IT** Con la presente, Establishment Labs dichiara che l'apparecchiatura radio di tipo localizzatore di port Motiva Flora® MFPL-001 è conforme alla Direttiva 2014/53/UE. Il testo completo della dichiarazione di conformità UE è disponibile sul seguente sito web: / **LV** Ar šo Establishment Labs apliecina, ka radioiekārtas veida MFPL-001 Motiva Flora® pieslēgvietas meklētājs atbilst Direktīvas 2014/53/ES prasībām. Pilns ES atbilstības deklarācijas teksts ir pieejams šajā tīmekļa vietnē: / **LT** „Establishment Labs” pareiškia, kad radijo įrangos tipo „MFPL-001 Motiva Flora®” priedavado vietos nustatymo įtaisas atitinka Direktyvą 2014/53/ES. Visas ES atitikties deklaracijos teksto pasiekiamas toliau nurodytu interneto adresu: / **MT** Hawnhekk, Establishment Labs tiddikjara li t-tagħmir tar-radju tat-tip Lokalizzatur tal-Port ta' Motiva Flora® MFPL-001 hu konformi mad-Direttiva 2014/53/UE. It-test shiħ tad-dikjarazzjoni ta' konformità tal-UE jinsab disponibbli fuq l-indirizz tal-internet li ġej: / **PL** Establishment Labs deklaruje niniejszym, że lokalizator portu Motiva Flora® MFPL-001 będący urządzeniem radiowym spełnia wymagania określone w Dyrektywie 2014/53/UE. Pełny tekst deklaracji zgodności UE jest dostępny pod następującym adresem internetowym: / **PT** A Establishment Labs declara por este meio que o localizador de porta Motiva Flora® MFPL-001, um tipo de equipamento de rádio, está em conformidade com a Diretiva 2014/53/UE. O texto completo da declaração UE de conformidade está disponível no seguinte endereço da Internet: / **RO** Establishment Labs declară prin prezenta că echipamentul radio de tipul localizatorului de port Motiva Flora® MFPL-001 este în conformitate cu Directiva 2014/53/UE. Textul complet al declarației de conformitate UE este disponibil la următoare adresă de internet: / **SK** Spoločnosť Establishment Labs týmto vyhlasuje, že rádiové zariadenie typu lokátor portu Motiva Flora® MFPL-001 spĺňa smernicu 2014/53/EÚ. Úplný text EÚ vyhlásenia o zhode je k dispozícii na nasledujúcej internetovej adrese: / **SL** Družba Establishment Labs s tem izjavlja, da je radijska oprema vrste lokatorja vrat Motiva Flora® MFPL-001 skladna z Direktivo 2014/53/EU. Celotno besedilo izjave EU o skladnosti je na voljo na naslednjem internetnem naslovu: / **SV** Establishment Labs intygar härmed att radioutrustningen av typen MFPL-001 Motiva Flora® portlokaliserare överensstämmer med kraven i direktivet 2014/53/EU. Den fullständiga texten i EU-försäkran om överensstämmelse återfinns på följande internetadress: **<https://motiva.health/patients-motiva-experience/>**



www.motiva.health

DOC-038 Rev 8 - Draft
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Dec, 2022
P/N: IDP_ELPL_00_15



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2514 AP The Hague
The Netherlands



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www.motiva.health

