

SAFE, SIMPLE AND SMART TWO-PERSON PATIENT TRANSPORTATION



TWO PERSON CARRY AID

www.thefleetseat.com



July 2021 User Manual V2021.23

Disclaimer

This manual is intended to provide Fleetseat users with general instructions for the use, operation and maintenance of this device. The instructions contained in this manual are not all-inclusive, and the safe utilisation of this device is dependent on the judgement and discretion of its users. Fleetseat products should always be utilised in accordance with any applicable laws and or regulations. Prior to using Fleetseat products, it is strongly recommended that carriers undertake training, which should occur before any of the products in the range are employed in an actual situation. Users are also strongly encouraged to store this manual inside the Fleetseat carry pouch or somewhere else easily accessible to them and others. This will ensure new users will have access to it should the product be transferred to a new user or users. Should additional or replacement copies of this manual be required, please email your request to support@thefleetseat.com or visit our Frequency Asked Questions (FAO's) page on our website at https://thefleetseat.com/faas/.

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A. Description, Intended Purpose and Claimed Performance

Fleetseat is a lightweight, compact and portable Patient transportation aid. Operable by two Carriers, this device is made from bio-compatible materials and is ergonomically optimised to ensure maximum user safety and comfort.





Colour Option #1: Charcoal and Orange colour

Colour Option #2: Tactical Black colour

FLEETSEAT SPECIFICATIONS		
Length	1120mm	
Seat Width	620mm	
Seat depth	425mm	
Weight	0.75kg	
Weight Limit	160kg / 353lbs	





Intended Purpose

Before attempting to use **Fleetseat** people intending to use **Fleetseat** need to read this user manual in full.

Fleetseat is intended to be used in situations where a Two-Person Carry would traditionally be attempted/performed without assistance of any aid. It is intended to make transporting a person who is unable to walk by virtue of an injury to a lower limb or through infirmity easier for those tasked with transporting them. It is also intended to minimise or eliminate any unwanted, unnecessary or invasive contact between Carriers and the Patient being carried. Furthermore, it is also intended to raise/increase awareness of consent and Patient consent generally.

In certain circumstances **Fleetseat** may be used as an alternative to a stretcher or wheelchair, where:

- an immediate response is required, and a stretcher or wheelchair is unavailable;
- physical environment does not permit wheelchair or stretcher access (i.e. on rough or uneven surfaces, in confined space, etc.);
- when there is an insufficient number of people available to safely and effectively transport a Patient using a stretcher;
- a lower limb injury has been sustained and the Patient is able to hold themselves in a seated position comfortably.

Fleetseat is ergonomically and bio-mechanically superior to the two-person seated carry method.

Claimed Performance

For the carrier, **Fleetseat** offers a superior option to the traditional 'aidless' two-person seated carry method, as it makes it significantly easier and safer for them to transport an injured or infirm person. This is achieved through:

- a design which optimally distributes the Patients' weight across several points;
- a design which minimises spinal stress;
- a design which limits unnecessary load stress during the transportation process;
- · increasing the distance that can be comfortably covered
- reducing the effort and time it takes to transport a Patient over medium to long distances; and
- eliminating the need to touch the injured Patient in an invasive or unwanted way.

For the Patient, **Fleetseat** provides:

- greater stability while being transported;
- faster transportation away from danger,
- a reduction in time taken to receive further medical attention;
- a design which significantly reduces exposure to invasive, unwanted or inappropriate touching by the Carriers; and
- enhanced overall safety and comfort when compared with the traditional two-person-carry method.

Fleetseat has been manufactured with materials that are in common use for medical devices and of neutral biocompatibility for the intended users – both Carriers and Patients.

B. Intended Performance

Fleetseat is a registered medical device and has a designated product life. Please refer to the label to determine the expiry date of the device.

Fleetseat is capable of transporting a person weighing up to 160kg (353lbs).



Check Expiry Date before Use



Weight Limit: 160kg / 353lb

Although **Fleetseat** has the capacity to transport a Patient weighing up to 160kg (353lbs), Carriers should apply discretion and common sense when determining if the Patient's weight is within their personal carrying capability. Attempting to lift and carry a Patient who weighs too much for a carrier to comfortably carry poses a risk to both the Carriers and Patient being carried. As such Carriers should not attempt to transport a Patient who they think will be too heavy for them to comfortably and safely carry.

If at any time during either the lifting or carrying phases of the transportation process, the Carriers feel any pain or discomfort, they should discontinue using the device.

Fleetseat should always be used in accordance with applicable Occupation Health and Safety Laws.



WARNING Improper use of Fleetseat may cause injury. Please read Fleetseat user manual prior to use.

C. Intended User - Carriers

The Carriers are the intended operator of the device.

Fleetseat is intended for use in situations where a Two-Person Carry is required. Given this, it is intended that users include:

- Sports and athletic trainers;
- First responders;
- School staff:
- Health professionals;
- · First aid providers; and
- Others.

Carriers using **Fleetseat** should be physically fit and free from musculoskeletal conditions.



Two (2) Carriers required to operate **Fleetseat**.

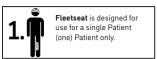


WARNING Improper use of **Fleetseat** may cause injury. Please read **Fleetseat** user manual prior to use.

D. Intended User - Patients

Fleetseat is designed for use with a single Patient.

Fleetseat is recommended for people who have suffered a lower limb injury or who are otherwise infirm.



Fleetseat should not be used if a Patient has or is suspected of having a head, neck or spinal injury.

Fleetseat should only be used if the Patient can assume a standing or semi-standing position.

If the Carriers are in any doubt as to the state of health of the Patient, then they should consult a healthcare professional before using Fleetseat.



See **WARNINGS** – General Safety Warnings. Page 24

E. Device & Contents

Purchasers of **Fleetseat** will be supplied with a **Fleetseat** and protective carrying pouch. Purchasers are also supplied with these Instructions for Use.

F. Operating Instructions

Also refer to <u>www.thefleetseat.com</u> for visual guides to operating **Fleetseat**.

Fleetseat comes assembled and ready for immediate use.

Users of the device should acquaint themselves with the full Instructions For Use and undertake practice or training exercises prior to using **Fleetseat**.

Safety Warnings

Carriers should be aware of the Safety Warnings listed in Section R.

Additional Instructions

If you require additional Instructions for using **Fleetseat**, you can access them at https://thefleetseat.com/online-instructions/ or contact support@thefleetseat.com

Patient Consent

Providing medical treatment to an injured person is an important role that comes with significant responsibilities, one of which is ensuring every possible step is taken to avoid causing harm to the injured person. This includes harm as a result of being touched in a way or on a part of their body they do not consent to. When a patient is touched in an unwanted and non-consensual manner, they can experience serious emotional distress and potentially sustain ongoing psychological trauma.

Fleetseat recognises the seriousness of this kind of harm and appreciates the lasting damage that it can cause. As a result, when designing this product, strenuous efforts were made to ensure that the potential for non-consensual touching of the patient was minimised to the greatest extent possible. This was primarily achieved by shaping the seat and positioning the handles in such a way that carriers can perform a two-person carry without needing to grab/hold under or in between the patient's legs.

Although **Fleetseat** removes the need for carriers to grab or hold the patient and significantly reduces the potential for the patient to experience unwanted touching by the carrier while being transported, some risk still remains. This risk can only be mitigated further if carriers make every effort to communicate to the patient prior to touching them what they intend to do and how they intend to do it. When this occurs and the patient consents, then and only then, is the risk of unwanted and non-consensual contact eliminated. Therefore, **Fleetseat** products should only be used after obtaining the consent of the patient.

Using Fleetseat

Position **Fleetseat** so the arrows next to the word 'front' are pointing forward.

1. Carrier 1 places a shoulder strap over their head and onto their outside shoulder so that, as the case may be, either the strap marked 'right shoulder' is sitting on their right shoulder or the strap marked 'left shoulder' is sitting on their left shoulder.



2. Carrier 2 puts the other shoulder strap over their head and onto their outside shoulder. Using the buckles on the straps the Carriers then adjust the straps so that they fit firmly to their bodies and so that, depending on their height relative to the height of the other carrier, the seat is positioned on or around their hips.



Carrying Patient

3. If the Patient is on the ground, the Carriers will need to squat down next to them and assist them into an upright seated position. From there, the Carriers help the Patient into a standing or semi standing position by lifting them up. This can be done in several ways including lifting them up by their arms. As the Carriers are doing this, they should instruct the Patient to place weight on their 'good' leg, to assist the lifting process.



4. When the Patient is in a semiupright position, instruction should be given for them to place their arms over the shoulders of the Carriers. The Carriers then slide the seat under the Patient's legs so that the front edge of the seat is close to the back of the Patient's knees. With the aid of the Carriers the Patient eases themselves on to the seat. Once the Patient is securely seated, the Carriers return to a fully upright standing position.



5. The Carriers now assess the comfort and stability of both the Patient and each other. If required, the Carriers can adjust the position of the Patient using the handles located on the front and back of the seat or those on the back of the shoulder straps.



6. Carriers assess the environment, confirm user comfort and, provided both Carriers and the Patient are safe, commence walking. Note: The transportation process is easier if Carriers take steps in unison, so it is recommended that Carriers use a '3 count' to commence the transportation process.

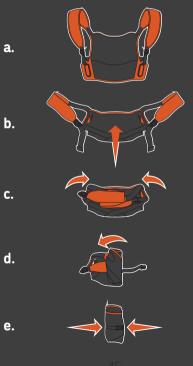


7. Upon reaching the destination, the Carriers lower the seat and assist the Patient back to a standing position. Depending on the circumstances, the Patient may require further assistance to safely sit or lie down.



Repacking

- a. Position **Fleetseat** so it is facing upwards, front towards you and straps to the side.
- b. Fold **Fleetseat** from front to back so that the clip is on the underside of the seat
- c. Place both straps on the seat.
- d. Roll the seat from one side to the other.
- e. Fasten the clip, tighten the strap and return **Fleetseat** to its pouch



Pre-deployment of Fleetseat

A key feature of **Fleetseat** is the ability for Carriers to wear **Fleetseat** on their body ready for quick deployment. For example, a Trainer at an organised sporting event can have **Fleetseat** on their person for fast use where an injury may be more likely. Wearing a **Fleetseat** can potentially commence carrying up to one (1) minute faster than without it being worn.

To wear **Fleetseat** ready for quick deployment, start by performing steps one (1) to three (3) as per above (page seven (7)). Once the strap is on Carrier one (1), place the other strap on the seat, before folding it and rolling it up from the opposite end as per step ten (10). Once rolled up, fasten the clip. At this point a carrier should be comfortably wearing the device. Should **Fleetseat** need to be deployed, the carrier can unfasten the clip and unroll the device so carrier two (2) can put it on. The Carriers are now up to step four (4) and should proceed as per the instructions above.

G. Sterility & Multiple Use

Fleetseat is rated as a non-sterile device.

There is no restriction on the number of times **Fleetseat** may be used provided the device has not been damaged and has not passed the product expiration date stated on the label.



Fleetseat is rated as a non-sterile device.

Fleetseat is designed for multiple uses, within adherence to the Cleaning, Maintenance and Storage requirements stated elsewhere in this Manual.



Refer to <u>Section N</u> for cleaning after each use of **Fleetseat**. Page 21.

H. Restrictions on Carriers & Patients

Carriers

Fleetseat works best when Carriers are of approximately the same height, weight and strength.

There may be times when there is a disparity in height between two Carriers. Provided this disparity is not greater than 30cm for average sized Carriers, **Fleetseat** may still be used safely. For this to occur, Carriers should adjust the height of the seat to a height which is comfortable for both Carriers.

If Carriers are unable to find a comfortable seat position due to their difference in height, **Fleetseat** should not be used.

Patients

Patients should be alert and/or physically able to stabilise themselves within the structure of the **Fleetseat**.



See **WARNINGS** – General Safety Warnings. Page 24

I. Maintenance

There are no consumable or replaceable items applicable to **Fleetseat**

Fleetseat should be regularly inspected, either after use or at regular intervals, to ensure the device, in whole or in part, is not damaged, torn, frayed, has become brittle or shows signs of contamination.

Fleetseat should be cleaned after each use in compliance with the Cleaning Instructions within this Manual.

Fleetseat should not be interfered with, maintained or cleaned whilst in immediate use with a Patient



See **WARNINGS** – General Safety Warnings. Page 24

J. Packing

Fleetseat should be repacked after use as per the Operating Instructions (Page 18) within this Manual.

Fleetseat should only be repacked after it has been cleaned in accordance with the Cleaning Instructions stated in this manual (Page 21).

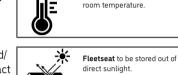
K. Storage and Preservation

Fleetseat should be stored in a clean and dry environment wherever possible.



Fleetseat should be stored at

Fleetseat should be stored at room temperature.



Direct sunlight exposure during pre-deployment and/ or normal use has no impact on **Fleetseat**. When not in use it is recommended that

Fleetseat be kept out of direct sunlight unless stored in its carry pouch.

If **Fleetseat** is used or has been exposed to a damp and/or dirty environment then the device must be cleaned in accordance with the Cleaning Instructions (Page 21) and dried before re-storing.

Fleetseat should be inspected for damage before being restored.

Any damage or material degradation may have an impact on the safety of the device. If this occurs the device should not be used.



L. Handling

Fleetseat should be handled in such a manner as to reduce or eliminate the possibility of damage to the product.

Do not use **Fleetseat** if it is damaged during handling.



M. Delivery

Please check your **Fleetseat** has been delivered in a complete and undamaged condition.

Please contact the manufacturer at support@thefleetseat.com if your **Fleetseat** has been damaged in transit.



See **WARNINGS** – General Safety Warnings. Page 24

N. Cleaning Methods & Contamination Risk Reduction

Clean and disinfect Fleetseat after each use.

Fleetseat can be cleaned using available domestic, commercial and hospital grade detergents and disinfectants.

Please follow the manufacturer's advice when using liquid based detergents and disinfectants when mixed with water.

Use of disinfectant wipes are suitable and recommended where there is no transfer of bodily fluids from users on to **Fleetseat**. **Fleetseat** should be cleaned with wipes with an active ingredient of 4.7 w/w or higher.

O. Product Serial Number, Batch Lot, Expiry Date and Other Identifiers

As a registered Medical Device, **Fleetseat** is required to state a Product Expiry Date. As the manufacturer does not control the level



of use, storage and other operational functionality related to **Fleetseat**, an expected product life after purchase has been calculated to allow for a reasonably heavy usage and low level of care over the life of the device.

Fleetseat has a Product Expiry Date of seven (7) years from Date of Manufacture.

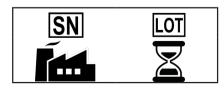
Fleetseat has an expected product life of five (5) years in use from Date of Purchase. Please replace your Fleetseat at the earlier occurrence of either the



Fleetseat's expiry date is seven (7) years from date of manufacture and five (5) years from date of purchase.

Product Expiry Date or five (5) years from the Date of Purchase.

Please check the label attached to your **Fleetseat** at the time of purchase for details relating to Device Serial Number, Batch Lot, Date of Manufacture and Product Expiry Date.



P. Risk from Interference

Fleetseat is not subject to any known interference or risk arising out of, or as a result of, exposure to electrical and/or other interference from electro-surgical devices, magnetic field interference from magnetic resonance imaging or other energy emitting devices.



See **WARNINGS** – General Safety Warnings. Page 24

Q. Bio-compatibility

Fleetseat has been extensively tested for bio-compatibility and exhibits no clinically adverse effects for Patient and Carriers under multiple and various tests in laboratory conditions per ISO 10993. **Fleetseat** is manufactured from PVC, Polyester Nylon and Plastic.

Fleetseat is not made with natural rubber latex.



Fleetseat is not made with natural rubber latex.



See **WARNINGS** – General Safety Warnings. Page 24

R. Warnings – General Safety Warnings

- Improper operation can cause injury. Operate Fleetseat only as described in this Manual. The manufacturer is not liable in circumstances where the device is used in a manner outside of that described in this Manual.
- Fleetseat should always be used in accordance with applicable Occupational Health and Safety Laws.
- Carriers should always seek and obtain the FULL PATIENT CONSENT before attempting to lift and carry them using a Fleetseat.
- Carriers should ensure they have practiced using Fleetseat prior to attempting to transport a Patient who is injured or infirm.
- Fleetseat is intended to be used by Carriers of approximately
 the same height. In instances where a height differential
 exists Carriers may still be able to safely use a Fleetseat. This,
 however, can only take place when the height differential
 between the Carriers is less than 30cm and when both
 Carriers are sufficiently comfortable despite any imbalances.
- Carriers can cause injury or be injured. Carriers should always maintain full control of the Fleetseat.
- If at any point during the transportation process a Carrier or Carriers feel continued use of the device is becoming unsafe then they should immediately cease using the device.

- Do not use Fleetseat as a Carrier if you are suffering from any condition that impacts on your personal lifting and carrying capacity (i.e. cardiac issues, back pain, asthma, etc).
- Do not use the Fleetseat in circumstances where the Patient is not alert and/or is not physically able to stabilise themselves within the structure of the device.
- Do not use the Fleetseat to transport a person whose weight is greater than 160kg (353lbs).
- Do not use the Fleetseat if the Patient is unable to be safely brought to either a standing or semi-upright position.
- Do not use the Fleetseat if the Patient has sustained a head, neck or spinal injury. Seek immediate medical assistance from a trained and suitable practitioner.
- Do not use the Fleetseat if the product has been damaged during use or handling. Maintain the device as described in the Manual.
- Do not use the Fleetseat after the earlier of the Product Expiry Date or a five (5) year period from Date of Purchase.
- Store the Fleetseat in accordance the directions contained in these Instructions For Use.
- Ensure Cleaning directions for the Fleetseat are adhered to.
- Do not modify or alter the Fleetseat in any way.
- Do not use Fleetseat on uneven or slippery surfaces.

S. Warnings – Undesirable Side Effects

- Fleetseat is manufactured using synthetic blends and/or plastic derivatives that are in common use in medical devices.
 Sensitivity to PVC, Nylon or other synthetic blends may result in a rash or irritation.
- If a moderate or severe skin irritation or rash appears on either Carriers or Patient then use of Fleetseat should cease immediately.

T. Complaints or Product Issues

Should any purchaser of Fleetseat have an issue or serious incident with the product, please contact: support@thefleetseat.com and provide the details of the issue, serial number and purchaser details.

The serial number is located on the label attached to the device on the shoulder strap of the device.

U. Manufacturer & Product Regulatory Details

Meditech 4 Sports Pty Ltd ABN 15 618 665 348 4 Robinson St Malvern, VIC 3144 Australia Ph 1300 652 396



Fleetseat is manufactured in Australia by Meditech 4 Sport Ptv Ltd.



Enquiries: info@thefleetseat.com



Fleetseat can be contacted via website, email and phone.

Within Australia

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Patent Pending 2020903214

<u>Design Registration</u> 202014912

Australian Register of Therapeutic Goods 366590

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Internationally

Fleetseat has international Intellectual Property protections for Patent (Pending), Trademarks and Design Registrations under application and/or registered both under and utilising the Madrid Protocol and within individual countries and/or regions including but not limited to; New Zealand, United State of America, Canada, European Union, Great Britain (UK), Japan, Singapore, India and Others.