



Playpak

User Manual



Family Freedom



Playpak is a 'portable activity kit' that helps babies and young children develop through play.

Please read all instructions carefully before using your Playpak. All instructions can also be found on our website **firefly.sunrisemedical.com** along with videos, diagrams and FAQ's.

Contents

01 Intended Use	p.03
02 Declaration of Conformity	p.03
03 Warnings and Cautions	p.03
04 Terms of Warranty	p.05
05 Safety Information	p.05
06 Precautions and Contraindications	p.06
07 Cleaning and Care Information	p.07
08 Daily Product Inspection	p.08
09 Reissuing Firefly Products	p.09
10 Product Servicing	p.09
11 Instructions for use	p.10
12 How to use your Playpak	p.11
13 Technical Information	p.13
14 Table of Symbols	p.14

SECTION 01: Intended Use

Intended use

Playpak is intended to facilitate early intervention therapy at home or on the move for children aged 0-48 months who have mild to complex postural needs that affect the ability to maintain a developmental position without external support.

Indications for use

Playpak is a portable activity kit that lets kids develop through play. This lightweight bag unfolds to produce an entire activity centre that has been designed for special needs babies and kids ranging from birth to approximately 48 months and Gross Motor Function Classification Scale (GMFCS) levels I-V, depending on their level of physical development.

SECTION 02: Declaration of Conformity

The Playpak is classified as a Class I Medical Device under EU and UK regulations. James Leckey Design Ltd as manufacturer with sole responsibility declares that the Firefly Playpak conforms to the requirements of the 93/42/EEC Guidelines, Medical Device Regulations 2017, UK Medical Devices Regulation 2002 and EN 12182

Technical aids for disabled persons and test methods.

Notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

NOTE:

General user advice.

Not following these instructions may result in physical injury, damage to the product or damage to the environment!

SECTION 03: Warnings and Cautions

Warning Occupant Security

- Ensure that all components, supports and straps are securely applied.
- If the user exhibits any form of distress, remove from the product as quickly as is safely possible.
- Users should not be left unattended at any time whilst using Leckey equipment.

- Ensure sufficient clearance of any straps from the user's neck, during use of the product and transfers, to avoid any strangulation risk.

Warning SIDS Hazard

- Do not let infants sleep in the equipment due to risk of SIDS.

Warning Finger Pinch Hazard

- While the user is in the product, the carer should strive to keep product adjustments to a minimum.
- Take care not to nip fingers when opening and closing zippers.

Caution Skin Irritation Hazard

- While the user is in the product, the carer should strive to keep product adjustments to a minimum.
- Ensure zip slider and chain are covered before use to avoid the user getting scratched.
- Ensure hooky Velcro components face away from user at all times.

Caution Daily Checks

- The product is to be checked daily before use to ensure that all components are securely attached and safe for use.

Caution Cleaning

- Clean the product regularly to prevent the build-up of dirt.

Accumulated dirt can prematurely wear the fabric components. Only use non-abrasive household cleaners and moist cloths, do not use running water on the upholstery whilst it is still attached to the product. See Cleaning and Care Information of the user manual.

Caution Cleaning Power Washer/ Hoses

- Hoses and power washers are not to be used to clean the product. See Cleaning and Care Information of the user manual.

Caution Disposal

- When disposing of the product using a community waste disposal site, the components should be disposed of separately where appropriate.

SECTION 04: Terms of Warranty

UK / ROI: Goods can be returned to us for warranty repair or replacement up to 12 months from receipt. In all cases, it is the customer's responsibility to ensure the goods being returned are suitably packaged, preferably in the original packaging.

International Customers: Goods can be returned to us for warranty repair or replacement up to 12 months from receipt. Please contact us to obtain a case reference ID as per the International Returns procedure. The customer is responsible for the cost of returning the goods. Once returned to us we will repair or replace your goods and return them to you within 14 days.

In all cases, it is the customer's responsibility to ensure the goods being returned are suitably packaged, preferably in the original packaging.

SECTION 05: Safety Information

1. Always read user instructions fully before use.
2. Do not modify your Playpak or use components other than Firefly recommended components with it at any time. Playpak should not be used if any of its components are faulty.
3. Always use the bag/mat as a floor mat base of support and never use the other components on their own.
4. Remove shoulder strap before product use.
5. Playpak has been designed for indoor use and when not in use should be stored carefully in a dry place that it not subject to extreme temperatures.
6. Always use Playpak on a level surface.
7. Carry out any positional adjustments and ensure that all Velcro is fully affixed before use – ensure your child is secure at all times.
8. Do not force positions with your child as you could harm them. Ensure that, for each activity you do with your child, you are using the correct and recommended components – for advice on this, see Section 12.2.
9. To avoid any rubbing or grazing of the skin, ensure that Velcro is placed away from the child at all times. If you notice any ongoing irritation as a result of using Playpak, discontinue use.
10. Do not leave your child unattended whilst using Playpak.
11. Playpak complies with fire safety regulations in accordance with EN1021-1. However the product should be kept away from naked flames.
12. Clean the product regularly in accordance with Section 7 of these user instructions. Do not use

abrasive cleaners and do not dry clean. Carry out maintenance checks on a regular basis to ensure your product is in good working condition.

13. Take care not to nip fingers or trap clothing when opening and closing zippers on bag – follow Section 12.2 for advice.
14. Ensure that your child is physically suitable for Playpak by noting the technical information in Section 13.
15. Failure to follow the user instructions may put you and/ or your child at risk.
16. If in any doubt about your ability to use Playpak safely, or if any parts should fail, please cease using the product immediately and contact Firefly Customer Services on UK 0800 318265 or ROI 1800 626020.

SECTION 06: Precautions and Contraindications

Precautions

- Fixed spinal deformities such as scoliosis or kyphosis
- Severe muscle contractures
- Severe muscular or skeletal asymmetry including hip dislocation
- Progressive and muscle wasting conditions
- High risk or recent history of bone fractures
- High risk of pressure related injury or open sores
- Strong, uncontrolled movement patterns
- Poorly controlled seizure activity
- Children dependent on the use of percutaneous endoscopic gastrostomy
- Medical instability including compromised respiratory or cardiovascular function
- Dependant on 3rd party life-sustaining apparatus such as oxygen tanks
- Significant learning disabilities and/or behavioural issues

Contraindications

There are no contraindications associated with Playpak.

As Playpak is deemed as low-level/non assessment product, all precautions and contraindications are taken at the discretion of the parent or prescribing clinician.

SECTION 07: Cleaning and care information

Bag/Mat

- The Playpak bag/mat can be individually placed into the washing machine and washed at 30°C.
- Whilst line drying is recommended, the Playpak bag/mat can be tumble dried at a low temperature.
- Do not dry clean.
- Do not bleach.
- Do not iron.
- Wash separately from other garments to avoid colour run.
- Staining should be removed as quickly as possible with an absorbent cloth, towels or a sponge. Routine soap and warm water sponging is effective for ordinary soiling and minor spills. Be careful not to

saturate the fabric as this will cause the stain to spread.

- Antiseptic cleaning agents can be used on more stubborn stains. These may require a safe solvent such as Isopropyl Alcohol or Mineral Spirit. Ensure that cleaning products are fully removed.

Components

- All upholstery can be removed from foam components, placed into the washing machine and washed at 40°C.
- Whilst line drying is recommended, the Playpak components upholstery can be tumble dried at a low temperature.
- Do not dry clean.
- Do not bleach.
- Do not iron.
- Wash separately from other garments to reduce risk of colour run.
- Staining should be removed as quickly as possible with absorbent cloth, towels or a sponge. Routine soap and warm water sponging is effective for ordinary soiling and minor spills. Be careful not to saturate the fabric as this will cause the stain to spread.
- Antiseptic cleaning agents can be used on more stubborn stains.

These may require a safe solvent such as Isopropyl Alcohol or Mineral Spirit. Ensure that cleaning products are fully removed.

Velcro

To ensure that Velcro remains 'sticky', remove any 'fluff' build up on a regular basis by using either a dry toothbrush, wire cat/dog brush or an adhesive lint roller.

SECTION 08: Daily Product Inspection

To ensure that Playpak is safe, we recommend that various checks are carried out before use.

The recommended checks are detailed below:

- Ensure that the 'stickiness' of the Velcro has not been compromised by a build-up of 'fluff'. Use a dry toothbrush, wire cat/dog brush or an adhesive lint roller to remove any 'fluff' from the bag/mat and components on a regular basis.
- Before you begin any activity with your child, ensure that you have all of the necessary components required to support them safely during that activity.

If in any doubt of the continued safe use of your Firefly product or if any parts should fail, please cease using the product and contact our customers services department as soon as possible.

SECTION 09: Re-issuing Firefly products

Before re-issuing a product, it is recommended that it is disinfected using one of the following procedures:

Note: Always clean the product first to remove accumulated soiling prior to disinfecting/sanitising.

1. Where possible, we recommend the use of an automated “fogger” disinfection system that is used to completely cover the product surfaces with a disinfectant agent. The manufacturer’s instructions for the chosen system should be referred to prior to use and followed exactly.
2. Where an automated disinfection system is not available, all product surfaces should be wiped over with disinfectant surface wipes or liquid disinfectant on a soft cloth. Suitable products are 70% IPA, 70% Alcohol or diluted bleach. The manufacturer’s instructions for the chosen product should be followed. Product upholstery and fabrics should be cleaned thoroughly in accordance with section, Cleaning and Care Information, of this manual.

Ensure a copy of the user manual is supplied with the product. If in any doubt of the continued safe use of your Firefly product or if any parts should fail, please cease using the product and contact our customer service department as soon as possible on UK 0800 318265 or ROI 1800 62602

SECTION 10: Product Servicing

Servicing of all Firefly products should only be carried out by technically competent persons who have been trained in the use of the product. This service is free of charge within the warranty period assuming the product has been used for the appropriate intended use. If the product falls outside of the warranty period, repairs will be chargeable. We may need to have the product returned to Firefly for further inspection which may incur a small fee for transportation. For all service related issues contact the Firefly customer service team on UK 0800 318265 or ROI 1800 626020.

SECTION 11: Instructions for use

How to know whether Playpak is suitable for your child

Every baby comes into the world with limited abilities, which is why the first four years of a child's life are the most important period of development. For some babies however, their new born limitations are not simply overcome by time. If a child's development is delayed for whatever reason, it means they are likely to acquire skills more slowly, or the extent to which they master a skill may vary.

Children with developmental delay, just like other children, learn through play. Fun through play can actually encourage children to work harder on therapy goals.

Playpak is a lightweight, portable entire activity centre that has been designed for special needs babies and kids ranging from birth to approximately 48 months and Gross Motor Function Classification Scale (GMFCS) levels I-V, depending on their level of physical development.

Its purpose is to assist your child to improve their physical, cognitive, sensory and prespeech communication abilities by enabling play in three key therapeutic positions which form the basis for later abilities - back lying (supine), tummy lying (prone) and floor sitting (long sitting).

It consists of rolls, wedges and supports, (designed by clinical experts) that stick together in dozens of ways and let your child tackle different developmental postures.

Playpak also comes with a handy online therapy guide, featuring advice and animated, easy-to-use instructions. These show you how to use each clever little piece to create different sitting and lying positions, as well as how to perform all the recommended developmental games with your child.

View and download the guide at firefly.sunrisemedical.com

You may find your child likes some positions more than others, or that some positions may not be medically recommended for your child. It is important that if in any doubt, you take advice from your therapist(s) about the best positions to place your child in.

This may depend on whether your child's muscles are tight (high tone) or floppy (low tone), their level of development or tolerance for certain positions. Some positions may need to be avoided for medical reasons, and others will need to be encouraged, even if your child is not keen at the start!

SECTION 12: Your Playpak

With your Playpak, you will receive:

Bag/Mat

The underside of your Playpak bag has a strip of non-slip fabric to help prevent the mat from sliding on smoother floor surfaces.



Rolls, (1x long and 1x short)

These rolls can be used on their own or with other support elements to provide just the right level of support.



Positioning Strap

Use this versatile strap in addition to the rolls for extra support when needed at the front, sides or back.



Head/Tummy Support

Can be used on its own to support head or trunk, or with other components for extra positioning possibilities.



Horseshoe Sitting Supports, (1x large and 1x small)

These profiled cushions are designed to give your child lower and upper back support, while allowing the hands to be free for play and function. When used in conjunction with the other elements, additional front, rear or side support can be increased.



SECTION 12.1: Packing your Playpak

- 1 Large Red Horsehoe
- 2 Small Green Horsehoe
- 3 Long Roll
- 4 Short Roll
- 5 Head / Tummy Support
- 6 Positioning Support



SECTION 12.2: How to use your Playpak

Information on tummy lying, back lying, floor sitting and general Playpak activities are all on our Youtube channel below:

www.youtube.com/user/fireflybylecky


















SECTION 13: Technical Information

	Length	Width	Depth
Folded Bag	44cm/17in	49cm/19in	15cm/5.9in
Unfolded Bag (Floor Mat)	134cm/53in	75cm/30in	NA
Long Roll	52cm/20in	9cm/3.5in	7cm/2.8in
Short Roll	28cm/11in	9cm/3.5in	7cm/2.8in
Positioning Strap	66cm/26in	8cm/3.1in	NA

	Length	Width	Depth	Angle
Head/Tummy Support	22cm/8.7in	26cm/10in	25cm/9.8in	65°

	Height	Depth	Min Seat Width	Max Seat Width
Large horseshoe support	11cm/4.3in	10cm/3.9in	20cm/7.9in	25cm/9.8in
Small horseshoe support	7cm/2.8in	9cm/3.5in	20cm/7.9in	25cm/9.8in

SECTION 14: Table of Symbols

Symbol	Meaning
	Medical Device
	Read the Instructions for Use
	CE mark
	UKCA mark
	Warning
	Manufacturer
	Product Code
	Serial number
	Max occupancy weight
	Date of Manufacture
	Latex free
	Unique Device Identification
	Machine wash- water temperature 40°C
	Do not tumble dry
	Do not iron
	Do not bleach
	Do not dry-clean



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