

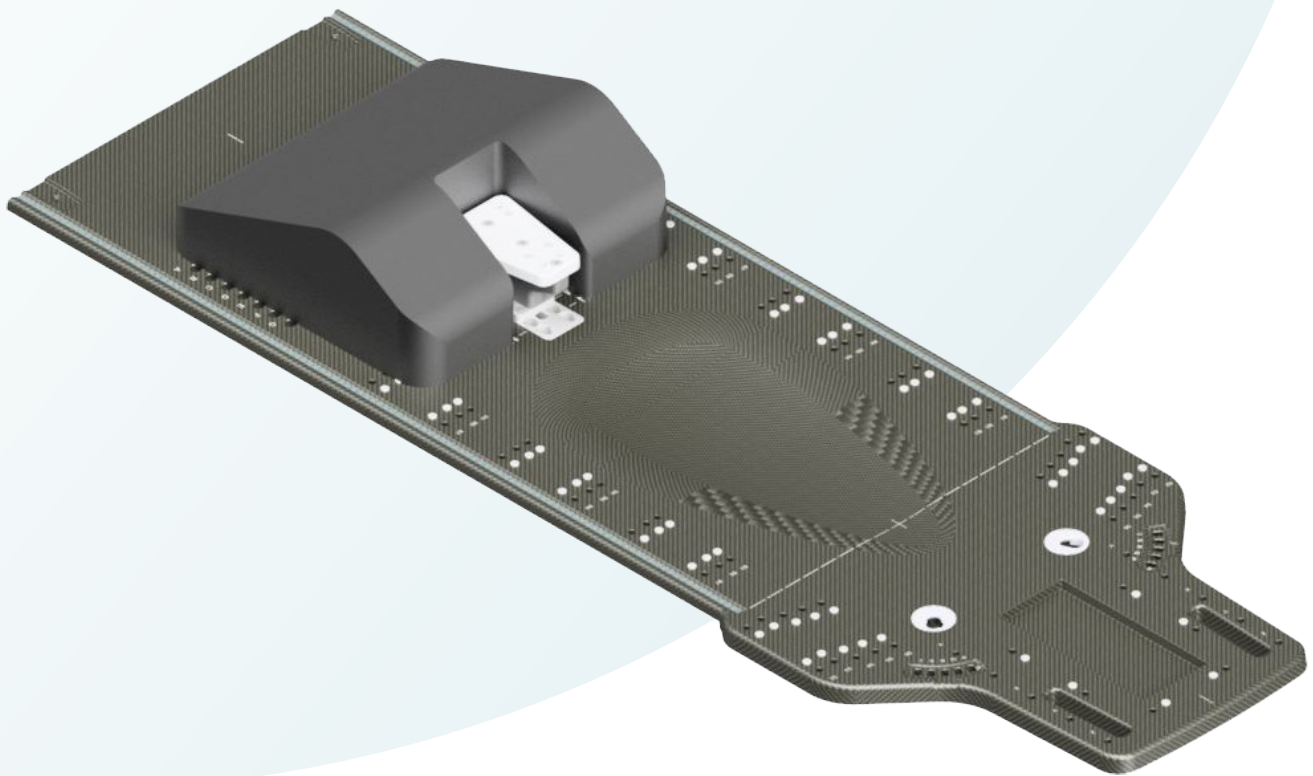


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SOLUTIONS IN RADIOTHERAPY

MANUAL 130160
Instructions for use
English Instructions

MacroMedics® KneeSupport for MiddleBlock



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Table of Contents

| | |
|--|---|
| 1. Warnings..... | 4 |
| 2. MRI Safety Information..... | 4 |
| 3. Intended Use..... | 4 |
| 4. Installation Instructions..... | 5 |
| 5. Cleaning, Storage and Disposal..... | 6 |
| 6. Warranty..... | 6 |
| 7. Notices..... | 6 |
| 8. Glossary of Symbols..... | 7 |

1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or if missing parts.
- Check individual components on MR-safety when used together in a patient positioning system.
- Avoid contact with any heat source.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. MRI Safety Information

MR SAFE

The following device is MR safe:

- 130160 KneeSupport For MiddleBlock



3. Intended Use

Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

4. Installation Instructions

Place the Kneesupport for Middleblock on top of a baseplate with a Middleblock as shown in figure 1 & 2.

Figure 1.

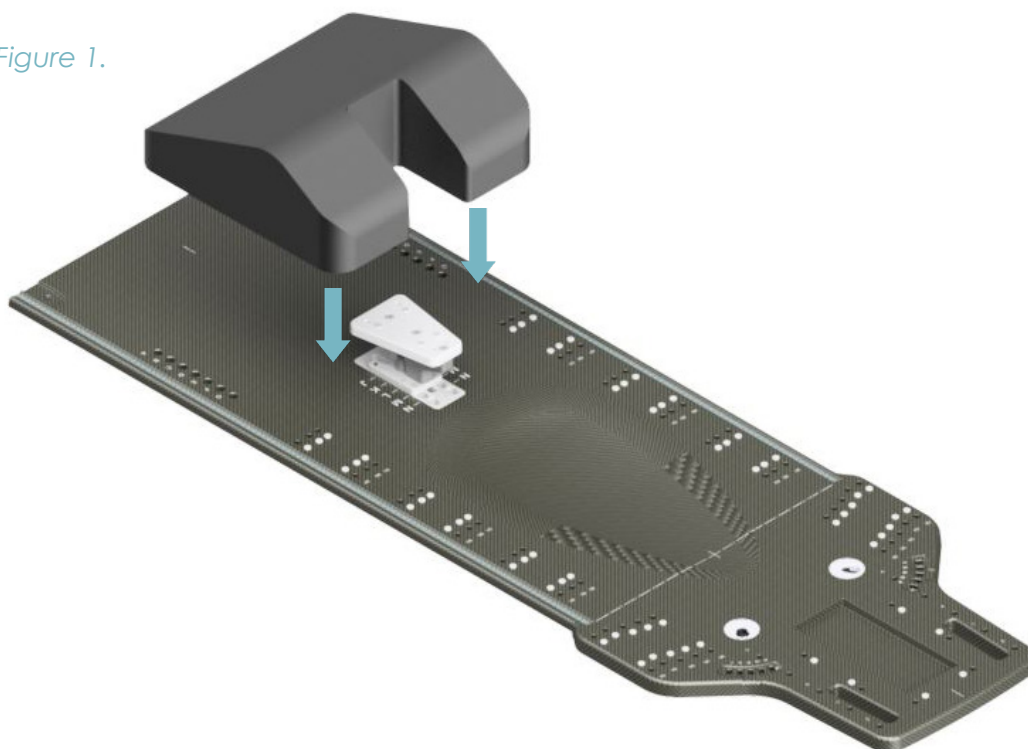
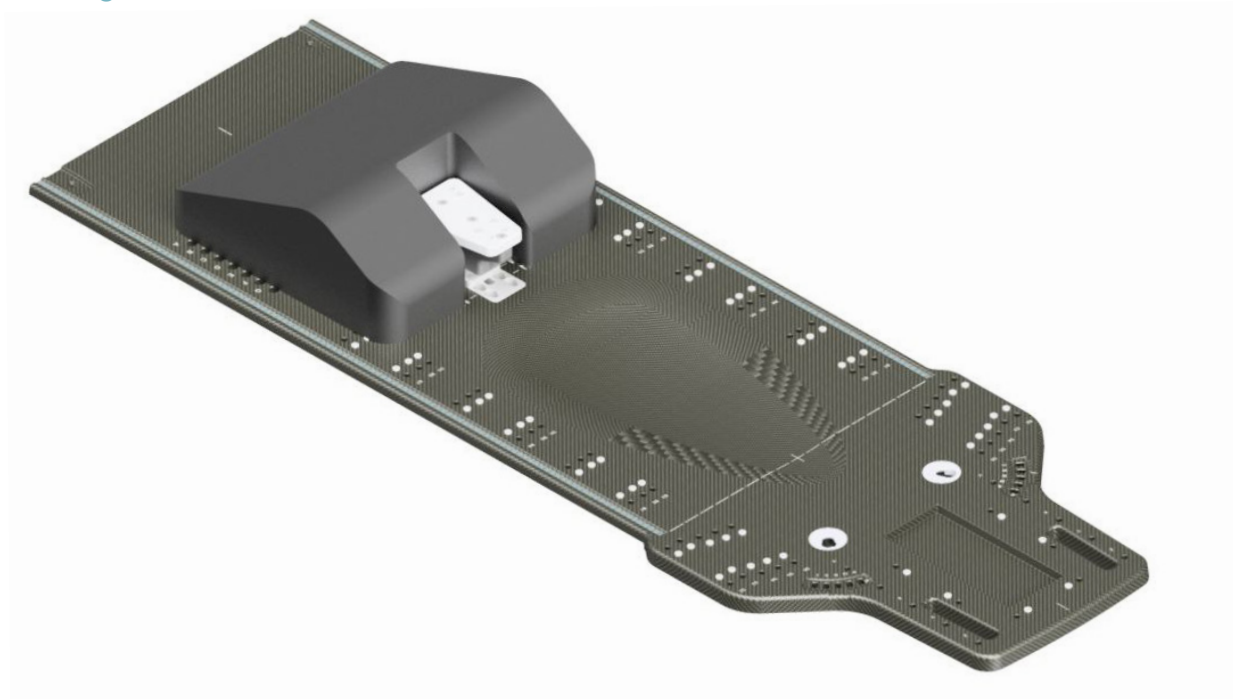


Figure 2.



5. Cleaning, Storage and Disposal

- Clean the device before and after every use with 70% Isopropanol or soapy water, applied with a soft cloth. Rinse with water and dry properly. Follow the cleaning precautions detailed on the bottle of the cleaning agent.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.
- Make sure that there is no residue of the cleaning agent left on the device prior to use.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the KneeSupport For MiddleBlock in a dry environment away from direct sunlight.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

6. Warranty

The MacroMedics products are warranted to be free from defects in manufacturing, material and construction. The warranty is for 1 year starting from the date of delivery.

Product warranties remain valid provided the product was installed and/or used according to the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorised alteration or repair are not warranted.

This warranty is limited to the repair and/or replacement at the sole discretion of MacroMedics.

7. Notices

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 or patient is established.

8. Glossary of Symbols

| Symbol | Symbol Name | Description of Symbol |
|--------------------|-----------------------------|---|
| | European Conformity | EC declaration of conformity by manufacturer. |
| | Manufacturer | Indicates the medical device manufacturer. |
| | Catalogue Number | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
| GS1 Code: (10) | Batch Code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| | Consult Instruction for Use | Indicates the need for the user to consult the instructions for use. |
| | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
| Rx ONLY | Prescription Only | Devices for sale to physicians or trained healthcare providers only. |
| | Keep Dry | Indicates a medical device that needs to be protected from moisture. |
| | Keep Away from Sunlight | Indicates a medical device that needs protection from light sources. |
| | MR Safe | An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic. |



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