



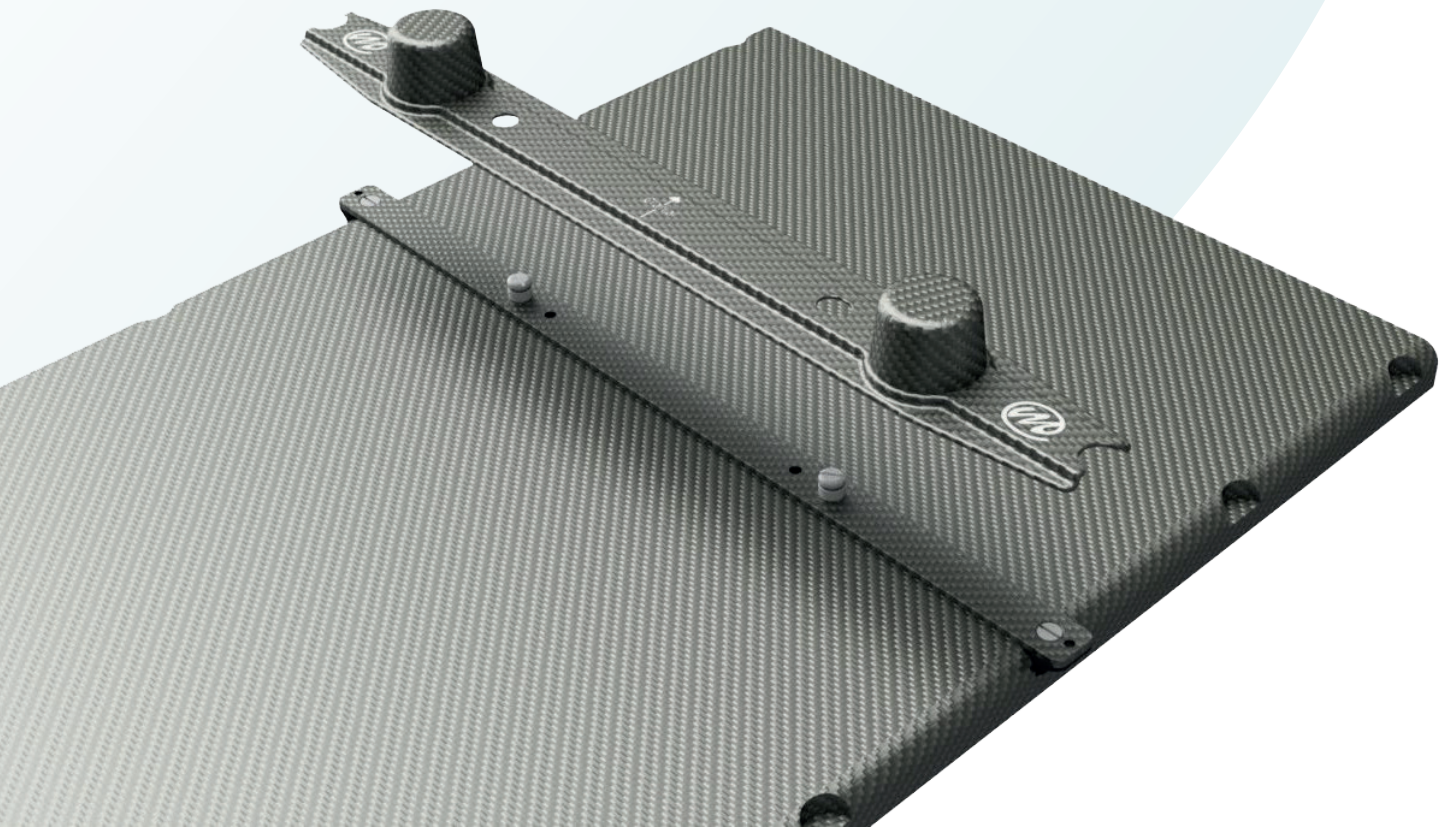
**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 147100  
Instructions for use  
English Instructions

## MacroMedics® CouchStrips & Sidepieces

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# 1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or incomplete.
- Check individual components on MR-Safety when used together in a patient positioning system
- Do not use MR Unsafe items in an MR environment.
- Handle with care to prevent damage.
- CouchStrips with low pivots should only be used with MacroMedics baseplates.
- HNS Baseplates and DSPS-Prominent® Baseplates only function with low pivot CouchStrips.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

# 2. MRI Safety Information

## 2.1 MR UNSAFE

The following devices are MR Unsafe:



- |                                    |                                     |
|------------------------------------|-------------------------------------|
| • 147110 CouchStrip CS53FCF-IB     | • 147450 CouchStrip CS53THCF-IB     |
| • 147130 CouchStrip CS53FCF-S      | • 147460 CouchStrip CS53THCF-S      |
| • 147140 CouchStrip CS50FCF-S      | • 147470 CouchStrip CS53THCF-EX     |
| • 147170 CouchStrip CS53FCF-PM     | • 147480 CouchStrip CS53THCF-PM     |
| • 147230 CouchStrip CS53TCF-S      | • 147490 CouchStrip CS53FHCF-EX/OB3 |
| • 147250 CouchStrip CS53TCF-EX     | • 147610 CouchStrip CSS51FCF-S      |
| • 147270 CouchStrip CS53TCF-PM     | • 147620 CouchStrip CSS51TCF-S      |
| • 147310 CouchStrip CS53TCF-P      | • 147630 CouchStrip CSS51FHCF-S     |
| • 147350 CouchStrip CS53TCF-IB     | • 147640 CouchStrip CSS51THCF-S     |
| • 147360 CouchStrip CS53FHCF-IB    | • 147660 CouchStrip CS53FHCF-PM     |
| • 147370 CouchStrip CS53FHCF-S     | • 147670 CouchStrip CS53THCF-P      |
| • 147380 CouchStrip CS50FHCF-S     | • 147680 CouchStrip CS53FHCF-P      |
| • 147390 CouchStrip CS53FCF-EX/OB3 | • 147950 CouchStrip CS50FCF-EX      |
| • 147430 CouchStrip CS50FHCF-EX    | • 147960 CouchStrip CS53FCF-EX      |
| • 147440 CouchStrip CS53FHCF-EX    | • 155870 VacuumCushion Pos.Strip    |

## 2.2 MR SAFE

The following devices are MR Safe:

- 147150 CouchStrip CS53FGF-S
- 147410 CouchStrip CS53FGF-PRO
- 147420 CouchStrip CS53FHGF-EX
- 147650 CouchStrip CS53FHGF-S
- 147930 CouchStrip CS53FGF-EX
- 155950 VacuumCushion Pos.Strip MR
- 164170 MRIdian 2-Pin Rail Cranial
- 164180 MRIdian 3-Pin Rail

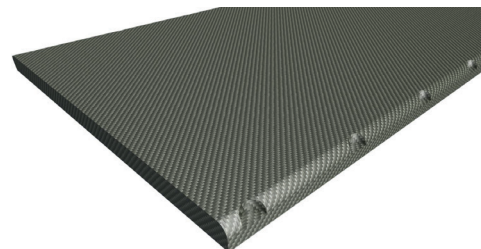


# 3. Intended Use

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

## 4. CouchStrip Overview & Placement Instructions

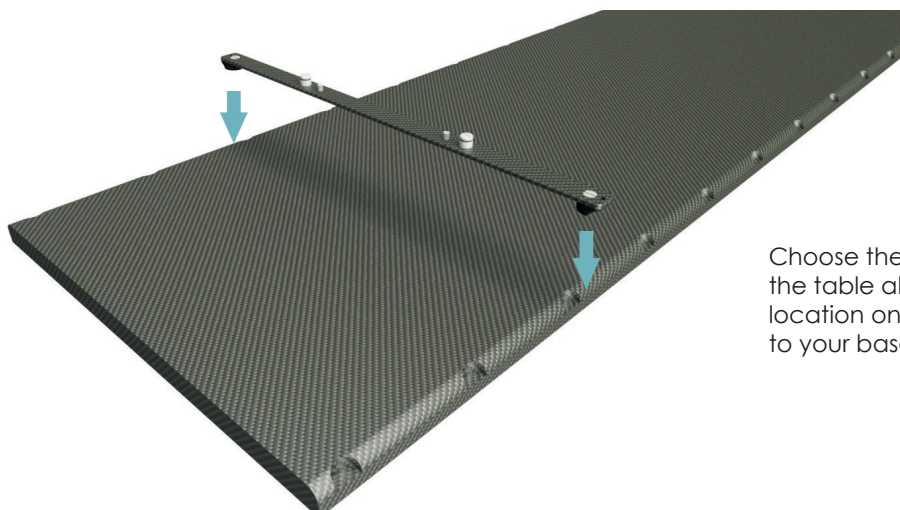
Use the following subchapters to determine the correct CouchStrips for your baseplate. The CouchStrips can be fixed onto MacroMedics 2- and 3-pin devices by using the included screws.



### 4.1 EXACT COUCHSTRIP

Table 1: Exact Indexed CouchStrips

Code	Type	Name	Material	Configuration	Couch Width (mm)	Pivot Type
147960	CS53FCF-EX	Exact couchstrip Fixed 530, CF	Carbon Fiber	Fixed	530	Low Pivot
147950	CS50FCF-EX	Exact couchstrip Fixed 500, CF	Carbon Fiber	Fixed	500	Low Pivot
147390	CS53FCF-EX/OB3	Exact couchstrip for OB3.0 530, CF	Carbon Fiber	Fixed	530	Low Pivot
147440	CS53FHCF-EX	Exact couchstrip Fixed 530, CF	Carbon fiber	Fixed	530	High Pivot
147430	CS50FHCF-EX	Exact couchstrip Fixed 500, CF	Carbon fiber	Fixed	500	High Pivot
147490	CS53FHCF-EX/OB3	Exact couchstrip for OB3.0 530, CF	Carbon Fiber	Fixed	530	High Pivot
147250	CS53TCF-EX	Exact couchstrip Transverse 530, CF	Carbon Fiber	Transverse	530	Low Pivot
147470	CS53THCF-EX	Exact couchstrip Transverse 530, CF	Carbon Fiber	Transverse	530	High Pivot
147930	CS53FGF-EX	Exact CouchStrip Fixed 530, GF for MR	Glass Fiber	Fixed	530	Low Pivot
147420	CS53FHGF-EX	Exact couchstrip Fixed 530, GF for MR	Glass Fiber	Fixed	530	High Pivot



Choose the corresponding CouchStrip using the table above. Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.

## 4.2 MEDICAL INTELLIGENCE COUCHSTRIPS

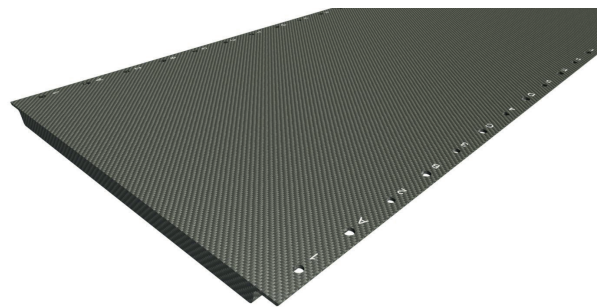
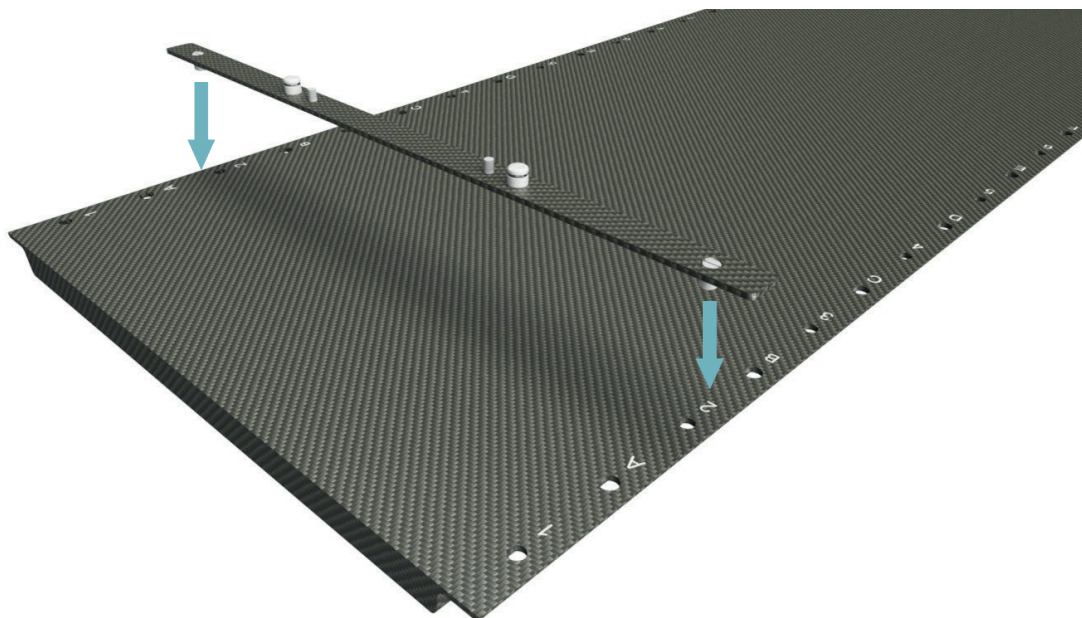


Table 2: Medical Intelligence Indexed CouchStrips

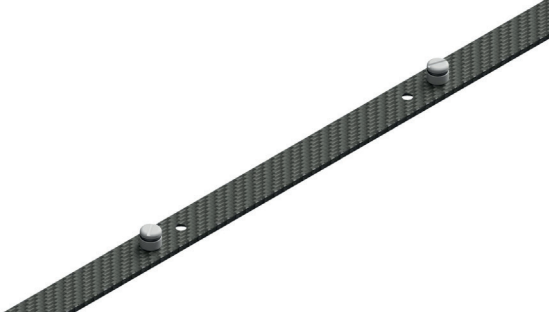
Code	Type	Name	Material	Configuration	Couch Width (mm)	Pivot Type
147110	CS53FCF-IB	Ibeam® Couchstrip Fixed 530, CF	Carbon Fiber	Fixed	530	Low Pivot
147360	CS53FHCF-IB	Ibeam® Couchstrip Fixed 530, CF	Carbon Fiber	Fixed	530	High Pivot
147350	CS53TCF-IB	Ibeam® Couchstrip Transverse 530, CF	Carbon Fiber	Transverse	530	Low Pivot
147450	CS53THCF-IB	Ibeam® Couchstrip Transverse 530, CF	Carbon fiber	Transverse	530	High Pivot

Choose the corresponding CouchStrip using the table above. Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.

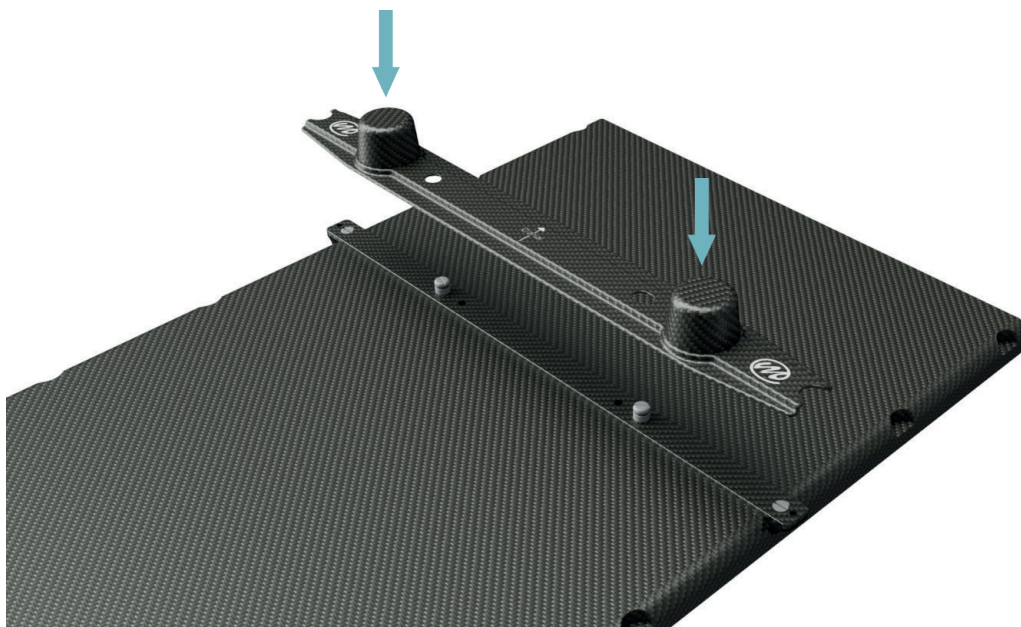


### 4.3 VACUUM CUSHION POSITIONING STRIP

Table 3: Vacuum Cushion Positioning Strips

Codes	Product Name	Indexing Style	Picture Indexing
155870	Vacuum cushion positioning strip, CF	Pivot	
155950	Vacuum cushion positioning strip, GF for MR		

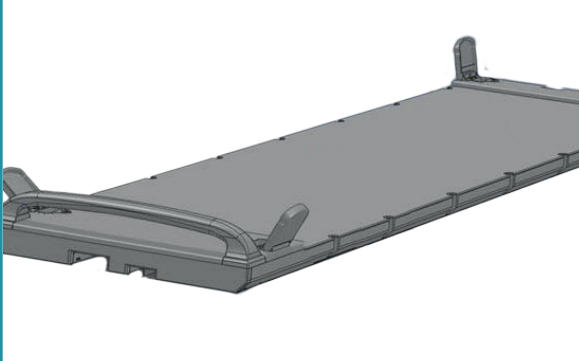
The Vacuum Cushion Positioning Strip is placed over a regular Couchstrip. Once the Vacuum Cushion Positioning Strip is in place, any MacroMedics Vacuum Cushion can be indexed by forming it around the knobs of the Vacuum Cushion Positioning Strip.



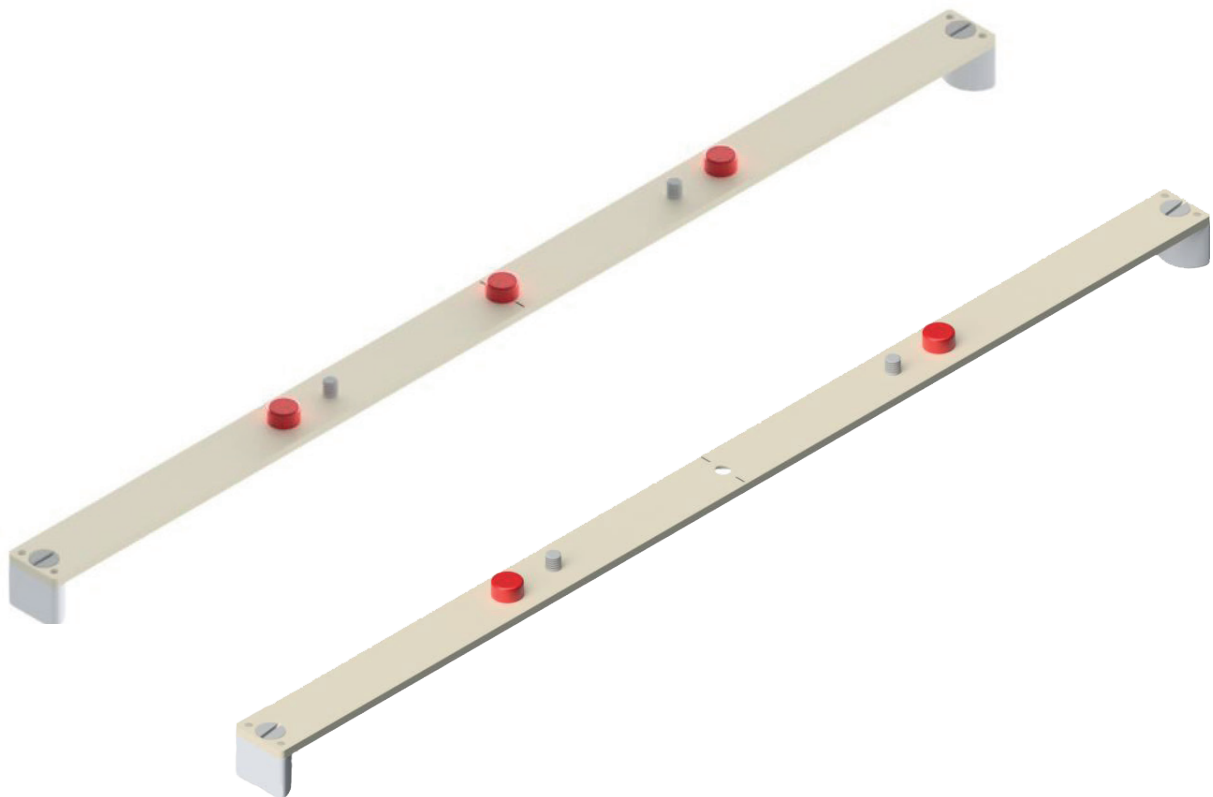


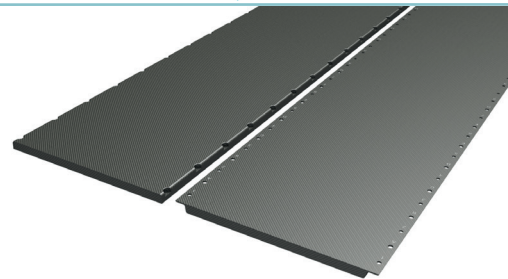
#### 4.4 MRIdian® COUCHSTRIPS

Table 4: MRIdian® CouchStrips

Codes	Product Name	Indexing Style	Picture Indexing
164170	MRIdian® 2-Pin Rail Cranial	Notch	
164180	MRIdian® 3-Pin Rail		

Choose the corresponding CouchStrip using the table above. Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.





## 4.5 SLIDING COUCHSTRIPS

Table 5: Sliding CouchStrips - General Indexing

Code	Type	Name	Material	Configuration	Couch Width (mm)	Pivot Type
147130	CS53FCF-S	Couchstrip Fixed 530 Sliding Sidepieces, CF	Carbon Fiber	Fixed	530	Low Pivot
147140	CS50FCF-S	Couchstrip Fixed 500 Sliding Sidepieces, CF	Carbon Fiber	Fixed	500	Low Pivot
147370	CS53FHCF-S	Couchstrip Fixed 530 Sliding Sidepieces, CF	Carbon Fiber	Fixed	530	High Pivot
147380	CS50FHCF-S	Couchstrip Fixed 500 Sliding Sidepieces, CF	Carbon fiber	Fixed	500	High Pivot
147230	CS53TCF-S	Couchstrip Transverse 530 Sliding Sidepieces, CF	Carbon fiber	Transverse	530	Low Pivot
147460	CS53THCF-S	Couchstrip Transverse 530 Sliding Sidepieces, CF	Carbon Fiber	Transverse	530	High Pivot
147150	CS53FGF-S	Couchstrip Fixed 530 Sliding Sidepieces, GF for MR	Glass Fiber	Fixed	530	Low Pivot
147650	CS53FHGF-S	Couchstrip Fixed 530 Sliding Sidepieces, GF for MR	Glass fiber	Fixed	530	High Pivot

Table 6: Siemens CouchStrips - General Indexing

Code	Type	Name	Material	Configuration	Couch Width (mm)	Pivot Type
147610	CSS51FCF-S	Couchstrip Siemens Fixed 514 Sliding Sidepieces, CF	Carbon Fiber	Fixed	514	Low Pivot
147630	CSS51FHCF-S	Couchstrip Siemens Fixed 514 Sliding Sidepieces, CF	Carbon Fiber	Fixed	514	High Pivot
147620	CSS51TCF-S	Couchstrip Siemens Transverse 514 Sliding Sidepieces, CF	Carbon Fiber	Transverse	514	Low Pivot
147640	CSS51THCF-S	Couchstrip Siemens Transverse 514 Sliding Sidepieces, CF	Carbon Fiber	Transverse	514	High Pivot

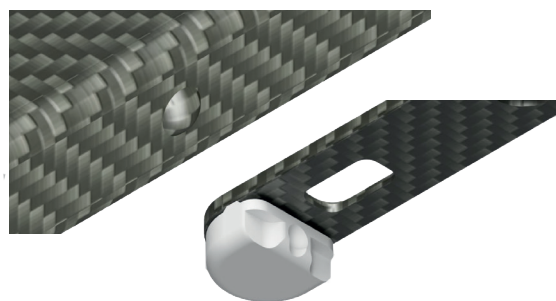
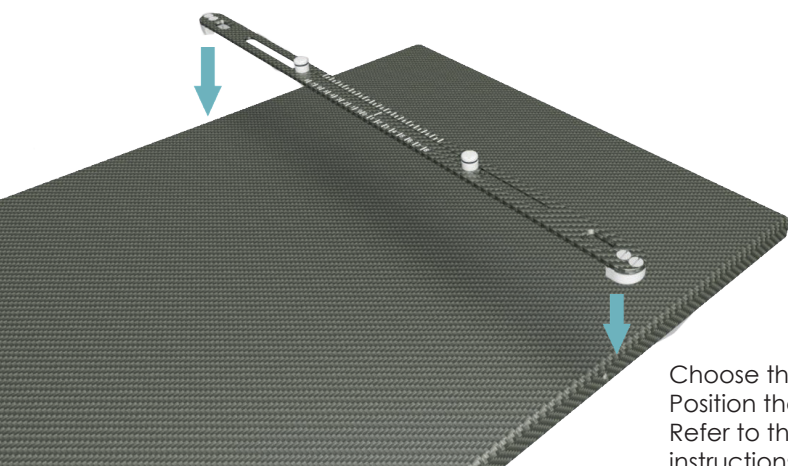


Choose the corresponding CouchStrip using the table above. Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.

## 4.6 PRODIGY™ COUCHSTRIPS

Table 7: Prodigy™ Mini Indexed CouchStrips

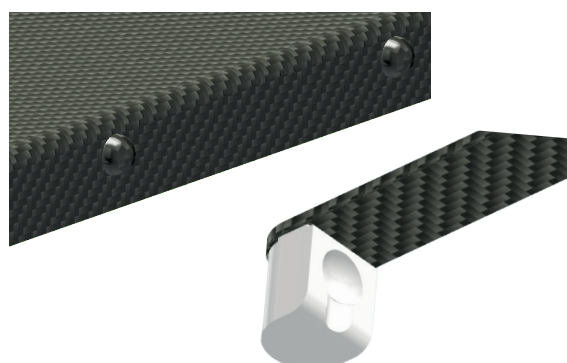
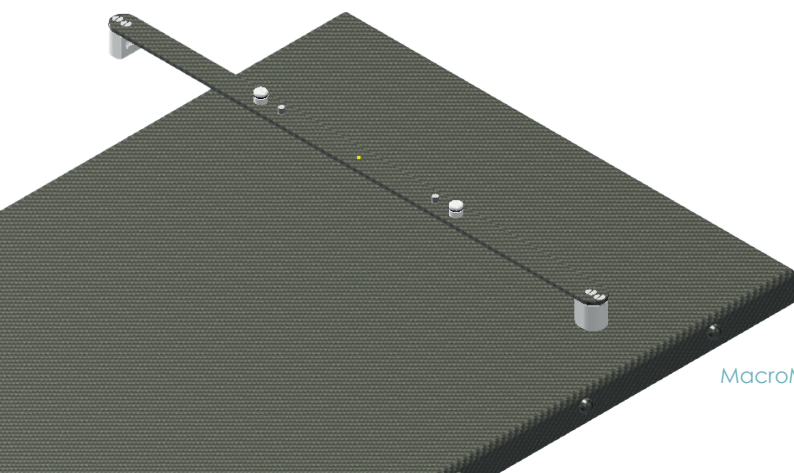
Code	Type	Name	Material	Configuration	Couch Width (mm)	Pivot Type
147170	CS53FCF-PM	Prodigy™ Mini Couchstrip Fixed 530, CF	Carbon Fiber	Fixed	530	Low Pivot
147660	CS53FHCF-PM	Prodigy™ Mini Couchstrip Fixed 530, CF	Carbon Fiber	Fixed	530	High Pivot
147270	CS53TCF-PM	Prodigy™ Mini Couchstrip Transverse 530, CF	Carbon Fiber	Transverse	530	Low Pivot
147480	CS53THCF-PM	Prodigy™ Mini Couchstrip Transverse 530, CF	Carbon Fiber	Transverse	530	High Pivot



Choose the corresponding CouchStrip using the table above. Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.


Table 8: Prodigy™ Indexed CouchStrips

Code	Type	Name	Configuration	Material	Couch Width (mm)	Pivot Type
147190	CS53FCF-P	Prodigy™ Couchstrip Fixed 530, CF	Fixed	Carbon Fiber	530	Low Pivot
147680	CS53FHCF-P	Prodigy™ Couchstrip Fixed 530, CF	Fixed	Carbon Fiber	530	High Pivot
147310	CS53TCF-P	Prodigy™ Couchstrip Transverse 530, CF	Transverse	Carbon Fiber	530	Low Pivot
147670	CS53THCF-P	Prodigy™ Couchstrip Transverse 530, CF	Transverse	Carbon Fiber	530	High Pivot

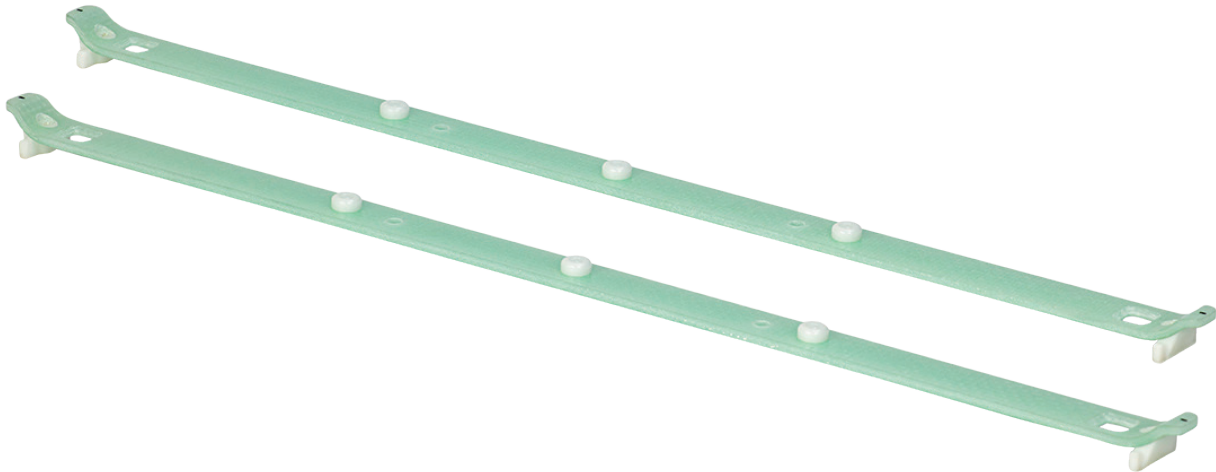


## 4.7 RT COUCHTOP XT TABLETOP COUCHSTRIPS

Table 9: RT CouchTop XT Tabletop CouchStrips

Codes	Product Name	Picture Indexing
147410	RT CouchTop XT TableTop CouchStrip Fixed 530, GF	

Position the CouchStrip in the desired location on the couch. Refer to the IFU corresponding to your baseplate for further instructions.



## 5. Cleaning, Storage and Disposal

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- 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.
- Having cleaned the device, perform a visual inspection of the device to ensure that it is thoroughly clean. If it is not, either repeat the cleaning process described above until the device is thoroughly clean upon visual inspection or dispose of the device to prevent the use of a soiled device.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the device in a clean, ventilated environment.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

## 6. Warranty

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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

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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.
 GSI 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.
<b>Rx ONLY</b>	Prescription Only	Devices for sale to physicians or trained healthcare providers only.
	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.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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