macromedics
SOLUTIONS IN RADIOTHERAPY

MANUAL 126270
Instructions for use
English Instructions

MacroMedics® Respiratory Suppression Belt

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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.
- The handpump and pressure gauge of the sphygmomanometer are not radiotranslucent as they contain metal parts. Therefore, keep the gauge/sphygmomanometer out of radiation pathway.
- Make sure that the device is securely fixed before positioning the patient. Place the patient carefully on the device and make sure that they lie down calmly. Instruct the patient not to reposition themselves after set-up.
- Do not overtighten the clamps, as this could result in damage to the product.
- Do not over-inflate the belt. Ensure that only the appropriate amount of pressure is applied, considering the clinical needs associated with the specific procedure being performed. Do not exceed a total pressure of 100mmHg.
- Ensure that the gauge and the connector of the air sack are outside of the region of interest during treatment/scanning.
- Avoid unnecessary vibrations to the gauge (e.g. falling from the table top or uncareful storage).
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

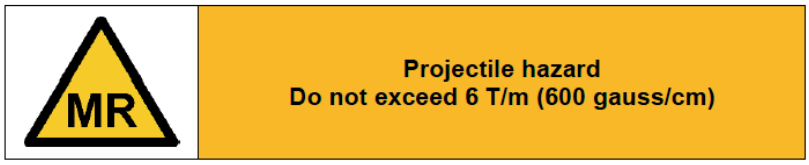
2. MRI Safety Information

2.1 MR CONDITIONAL

The following devices are MR Conditional:

- 126270 Respiratory Suppression Belt
- 126290 Respiratory Suppression Belt HXP

A patient with this device can be safely scanned in an MR system, meeting the following conditions:
- A Static Magnetic Field of 1.5 Tesla and 3 Tesla, with
- A Static Magnetic Field Strength (B0) of orientation: horizontal, cylindrical bore
- Maximum spatial field gradient (SFG) of 6 T/m (600 gauss/cm)



3. Intended Use

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

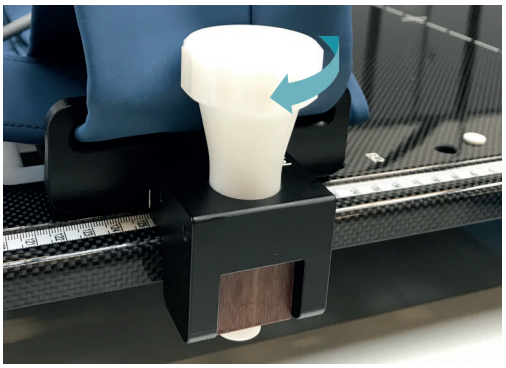
4. Use Instructions

The **126270** *Respiratory Suppression Belt* can be used with all MacroMedics baseplates with an integrated rail system.

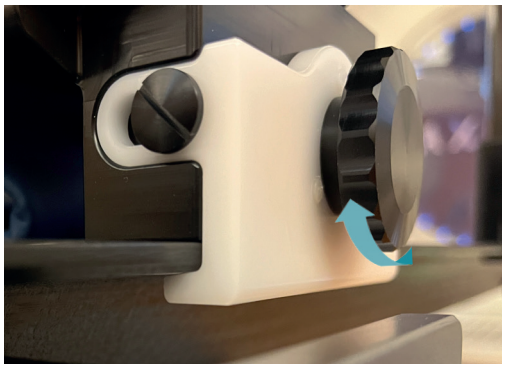
The **126290** *Respiratory Suppression Belt HXP* is to be used on the iBeam® couchtop.

I. Place the clamps (at either end of the belt) on the rail of the baseplate, in the desired position, and hook the clamps onto the side of the baseplate.

II. Turn the knobs clockwise to secure the belt in place. Do not overtighten the clamps, as this could result in damage to the product.



126270 *Respiratory Suppression Belt*



126290 *Respiratory Suppression Belt HXP*

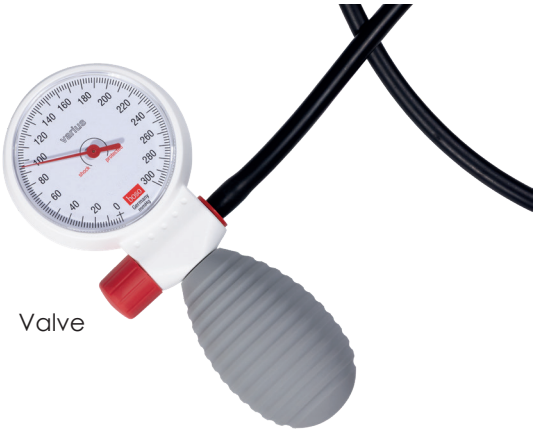
III. Unfix the velcro connecting the top straps of the Belt and lay the top straps to the side. Position the patient in the desired position, lying on the bottom part of the belt. As part of this, instruct the patient to not lean or pull on the knobs of the device as this can damage the device.

IV. Wrap the top straps of the belt around the patient and use the velcro to fasten the product in place. You may optionally take note of the scale (1 to 17) on the Belt to use as an indication for the (re-)placement of the strap.

V. Ensure that the valve (Red knob) is closed by turning it clockwise. Squeeze the handpump to inflate the belt.

Note: Do not over-inflate the belt. Ensure that only the appropriate amount of pressure is applied, considering the clinical needs associated with the specific procedure being performed. Do not exceed a total pressure of 100mmHg.

VI. Ensure that the patient is positioned comfortably.



Valve

VII. After inflation, you can disconnect the sphygmomanometer from the belt, preventing the sphygmomanometer from damage e.g. by accidentally falling from the treatment table.

To disconnect the sphygmomanometer from the belt, carefully push the blue knob on the (female) connector. During treatment, the sphygmomanometer can safely be stored in its dedicated casing.

VIII. To release the pressure and deflate the Respiratory Supression Belt, first reconnect the connectors if they have been disconnected. Then, turn the valve (Red knob) counterclockwise.

IX. To release the patient, detach the velcro straps. Instruct the patient not to pull themselves up using the knobs of the respiratory suppression belt as this can damage the device.

To release the Respiratory Suppression Belt from the baseplate, rotate the knobs counterclockwise and carefully lift the device off the table.

PLEASE NOTE:

A decrease in pressure reading can be observed on the sphygmomanometer as the Belt is in use with connectors. Do not worry, the pressure in the inflated cushion remains stable. What is occurring is that the part of the tube between the (female)connector and the sphygmomanometer is losing pressure, but from the (male)connector to the belt cushion remains stable at the correct pressure.

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 product.
- 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.
- 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.
- 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

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
CE	European Conformity	EC declaration of conformity by manufacturer.
	Manufacturer	Indicates the medical device manufacturer.
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
SN GS1 Code: (21)	Serial Number	Indicates the manufacturer's serial number so that a specific medical device 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.
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.

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