

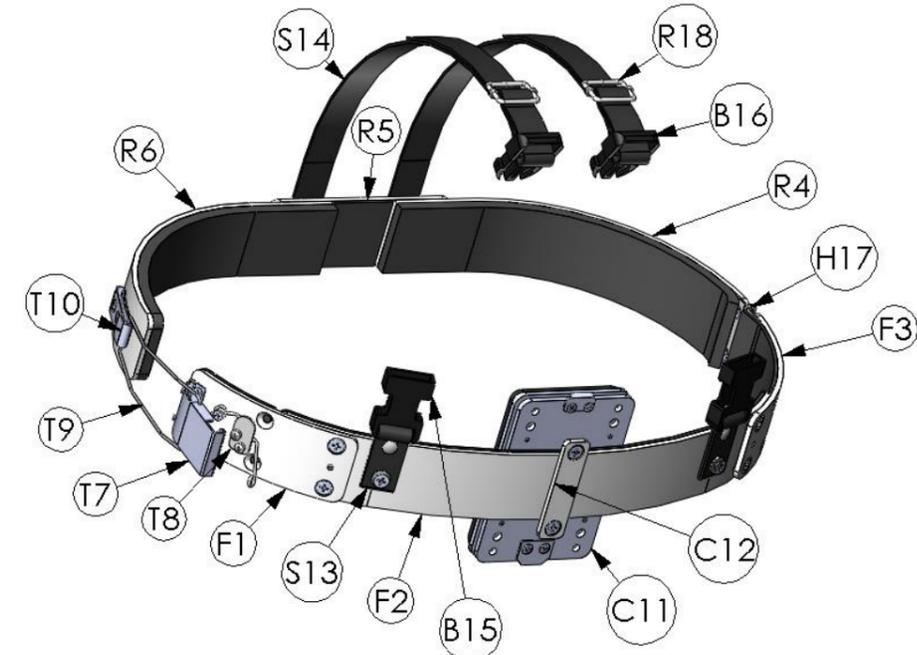
INSTRUCTIONS FOR USE: FMF® DYNAMIC COMPRESSOR SYSTEM BRACE

1. DESCRIPTION AND ASSEMBLY

The FMF® Dynamic Compressor System brace consists of 6 aluminium segments interconnected by means of screws. These segments are adjustable, enabling to increase or decrease the brace circumference so as to fit properly around the patient's chest.
 The 6 plates form 2 arches, an anterior and a posterior arch, are connected on one side by a hinge and on the other side by a latch-type fastener. The device also includes two adjustable straps to be placed over the shoulders and intended to maintain the brace at the proper height on the patient's chest. Finally, the system is completed by a compression plate that is attached to the brace and placed at the level of the deformity. This plate is used to maintain the necessary pressure to correct the defect.

Each brace has a label containing the following data:

Patient's name	
Pressure for Initial Correction	Pressure expressed in PSI
Manufacturing date	DD/MM/AAAA
FMF code:	B11-xx-xxx-xxx



Part number	Description
B15	Female plastic clip-on
B16	Male plastic clip-on
C11	Compression plate
C12	Compression plate mount
F1	Front plate, locking side
F2	Central front plate
F3	Front plate, hinge side
G19	Padding
H17	Side hinge
R4	Back plate, hinge side

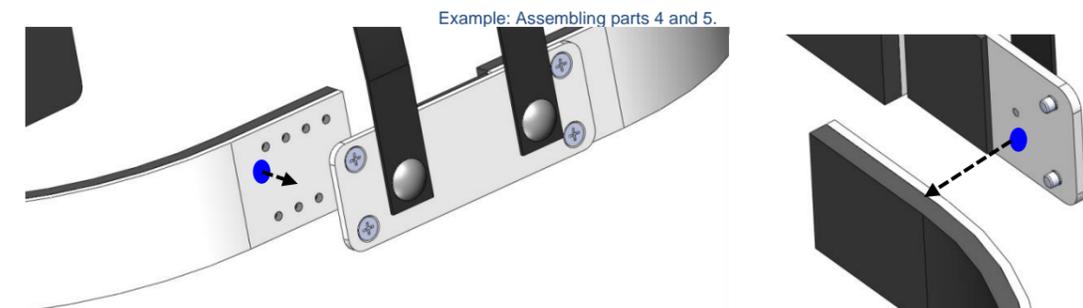
Part number	Description
R5	Central back plate
R6	Back plate, closing side
R18	Metal adjuster
S13	Front strap
S14	Back strap
S23	Set of straps
T7	Side closing
T8	Front plate of the side closing
T9	Latch wire
T10	Back plate of the side closing

The brace is delivered in five parts:
 Parts 1 and 2 are pre-assembled, together with the front part of the straps.
 Parts 3 and 4 are pre-assembled.
 Parts 5 (to which the back part of the strap is attached), 6 and 11 are separate.
 Sometimes parts 5 and 6 are pre-assembled.

Assembly is performed as follows:

- Assemble part 2 and part 3 using the 2 provided screws starting at the notch marked by a **red** point on the 2 parts (see the example above).
- Assemble part 4 and part 5 using the 2 provided screws starting at the notch marked by a **blue** point on the 2 parts (see the example above).
- Assemble (if necessary) part 5 and part 6 using the 2 provided screws, starting at the notch marked by a **yellow** point on the 2 parts (refer to the example above).
- Using the 2 screws, fasten the compression plate (part 11) to the front of the brace (part 2) using the plate mount (part 12).

When assembling the parts, make sure you use the correct colour code.



The screws must be tightened according to the above diagram. The notch marked with a blue point on part 4 corresponds to the hole indicated by the blue point mark on part 5.

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2. MAIN INDICATIONS

This product is intended for non-invasive treatment of pectus carinatum (PC) or "pigeon breast". It can also be used for the treatment of pectus arcuatum.

3. CONTRAINDICATIONS

This treatment does not guarantee good results for patients whose initial deformity correction pressure, as measured by the pressure sensor (Part No.: 36.415.91) is greater than 7.5 PSI. In such a case, either the deformity is too large, or the thoracic wall is not flexible enough and surgical treatment may be considered. Nevertheless, in consultation with the patient, the surgeon can still decide to perform treatment with the Dynamic Compressor System.

4. ADVERSE EFFECTS AND POSSIBLE COMPLICATIONS

- Discomfort
- Redness
- Skin discoloration
- Ulceration of skin
- Sores
- Irritations
- Respiratory discomfort
- Back and chest pain
- Wrong deformity correction.

If the patient experiences one or more of these side effects, contact the treating practitioner so appropriate measures can be taken. It should be noted that for pain relief, ibuprofen and paracetamol are usually sufficient.

For skin lesions, it is usually sufficient to apply a suitable cream locally and refrain from wearing the brace until the lesion has healed.

5. GENERAL INSTRUCTIONS FOR USE

At the first visit, the practitioner measures the Pressure for Initial Correction (PIC) and takes measurements of the thoracic wall. These data are entered in the prescription order sent to FMF and will be used to manufacture a custom-made brace.

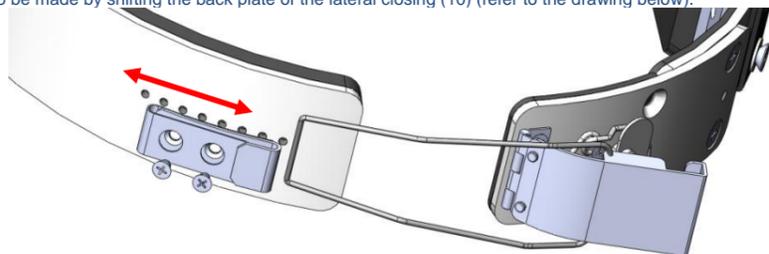
- The pressure for initial correction is measured using the pressure sensor (Part No. 36.415.91. Refer to the relevant Instructions for Use). The patient is placed with the back against a wall, facing the practitioner. The practitioner presses the pressure sensor on the deformity until a normal thoracic shape is obtained. The reading value is the pressure for initial correction. Take this measurement three times, then calculate the average of the measured values. If the PIC is lower than 10 PSI, treatment using the Dynamic Compression System is possible.
- The chest wall measurements are carried out using the thoracic wall ruler (Part No. 36.415.94) and a dressmaker's tape measure. Follow the Instructions for Use provided for the thorax ruler.

Proper use of the FMF brace involves performing the following steps:

1. Assemble the brace as described in paragraph 1 of this leaflet.
2. Place the brace over the patient's chest, without closing it. The lateral closure must be on the same side as the deformity. If the deformity is central, the position of the closure is at the practitioner's discretion and as is comfortable to the patient.
3. Fasten the straps and adjust their height so that the brace is at the height of the deformity.
4. Adjust the position of the compression plate (11) using its mount (12) so that the plate is located exactly over the deformity.
5. Close the brace using the lateral closing latch.
6. The brace has been fitted to the patient based on the measurements taken when placing the order. However, it is often necessary to make slight adjustments during brace installation. To do this, it is sufficient to change the relative position of the plates by using the different notches provided at each plate junction. In general, such adjustments are made between plates 1 and 2 and/or plates 2 and 3 (refer to the following drawing). Each notch represents an adjustment of 9 mm. The two provided screws should be used to fasten the two plates together.



Finer adjustments of 6 mm can also be made by shifting the back plate of the lateral closing (10) (refer to the drawing below).



7. After the brace has been set in place and correctly adjusted, check the pressure exerted on the thoracic wall, i.e., the Pressure of Correction (POC). To do this, mount the pressure sensor on the compression plate (11) (refer to the Instructions for Use of the pressure sensor). If the pressure exceeds 2.5 PSI, loosen the brace as explained in paragraph 6 of this section. If, on the contrary, the pressure is too low, the brace should be tightened (see paragraph 6). The applied pressure must be adjusted to the value determined by the practitioner. The recommended correction pressure is less than or equal to 2.5 PSI to avoid skin lesions and ensure better treatment tolerance by the patient.
8. The practitioner should keep the patient under observation for about two hours to make sure that the brace fits comfortably and the patient adjusts to the treatment. If necessary, the practitioner can make new adjustments.
9. After wearing the brace for a period of time, it will probably be necessary to make corrections in the curvature of the plates. This is due to the growth of the chest. In such a case, a manual bending device (Part No. 36.415.93) should be used to make the adjustments (see the picture below).



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10. If the patient's growth is significant, the brace may become too small, even after using all the possible corrections and adjustments. In such a case, some of the parts must be replaced by longer ones. In general, part 3 is replaced.
11. When the Pressure for Initial Correction (PIC), namely the pressure required to fully correct the deformity before starting treatment, is high (above 5 PSI), it is recommended to start the treatment at a pressure that is lower than the regular treatment pressure, i.e., at a pressure below 2.5 PSI. The pressure can be increased later. This will allow the patient to adapt to the treatment progressively.
12. It is recommended that the practitioner should check the pressure exerted by the brace on a monthly basis using the pressure sensor. The correction pressure may be reduced as the treatment progresses. During the control visits, the practitioner must also check the adjustment of the brace and its condition. This contributes to achieving proper correction of the deformity. These checks are particularly important during the first months of treatment.
13. The duration of the treatment depends on the patient and, in particular, on the initial correction pressure. The treatment may last from several months to more than one year. After the desired correction has been achieved, it is recommended to continue the treatment for another few weeks, to prevent recurrence. In case of recurrence, restart the treatment using the same brace if an adjustment is possible. If not, order longer parts or order a new brace.

Please note: All measurements must be taken using the pressure sensor (Part No. 36.415.91).

Important information regarding the use of the brace to be communicated to the patient or his caretakers.

- To ensure the success of the treatment, the brace must be worn as often as possible (up to 23 hours a day). It must be worn at all times, both during the daytime and at night. It should be removed only when washing or engaging in sports.
- The brace must be worn on the bare skin, or over a tight-fitting undershirt or T-shirt. The undershirt or T-shirt must be changed daily. Due to its fine structure, the brace can be discreetly worn under clothing.
- To reduce the risk of skin lesions, particular care must be paid to personal hygiene. The patient must take a bath or shower every day.
- The patient should avoid sleeping on the stomach during the entire duration of treatment.
- The occurrence of redness and pain, especially at the beginning of treatment, is normal. For pain relief, ibuprofen and paracetamol are generally sufficient. In the event of redness, the patient can perform a simple test. When pressing on the red area with the finger, the area should become white, then should turn red again after removing the finger. If the area remains red, do not put the brace on. Contact the practitioner.
- In certain cases, placing a foam pad on the mattress can improve the sleep of patients who have difficulty getting used to the brace.

6. PRECAUTIONS AND WARNINGS

- Watch out for any sign of patient discomfort while using the device.
- Make sure that the product conforms to the indications on the packaging.
- Proceed to a visual inspection of the device to detect possible damage that could compromise its normal operation.
- Do not let the device come into contact with surfaces or substances that could damage its surface.
- In case of serious damage or visible defect, do not use the device.
- If the manual bending device is found defective, please return it to the company.
- Our company shall not be responsible for any repairs of components performed by third parties.
- Make sure that the screws are properly tightened.
- This device must be used by a practitioner having appropriate training.
- This brace has been custom-made for a specific patient. It may not be worn by other patients.
- The device may not be assembled or modified by the patient. This must be done by the practitioner in charge of treatment only.
- Do not assemble components from different sources.
- Use only parts supplied by our company. Otherwise, we shall assume no responsibility.
- Do not leave the brace in proximity of a source of heat.

7. INTERFERENCE WITH OTHER MEDICAL TESTS OR TREATMENTS

During other medical tests, such as imaging tests, the brace must be removed.

8. HANDLING AND STORAGE

Fragile, handle with care.
 Store the products in their packaging.

9. MAINTENANCE

If necessary, the brace can be cleaned with soap and water. Rinse well. Dry completely before putting the brace on again. The patient or his caretakers must check the condition of the brace weekly. Any loose screws must be re-tightened using a suitable manual screwdriver only. If any screw is lost, take the brace to the practitioner for repair. Only the spare screws supplied with the brace may be used. If not available, you can request them from our company. Sometimes, the protective padding needs to be glued in place again. The bending device can be cleaned using a cloth soaked in alcohol.

10. EXPLANATION OF SYMBOLS

REF	Catalogue part number		Manufacturer		Please read the precautions for use		Lot number
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For additional information, please contact us or your dealer or consult the videos and documentation available at our website www.medicalex.info