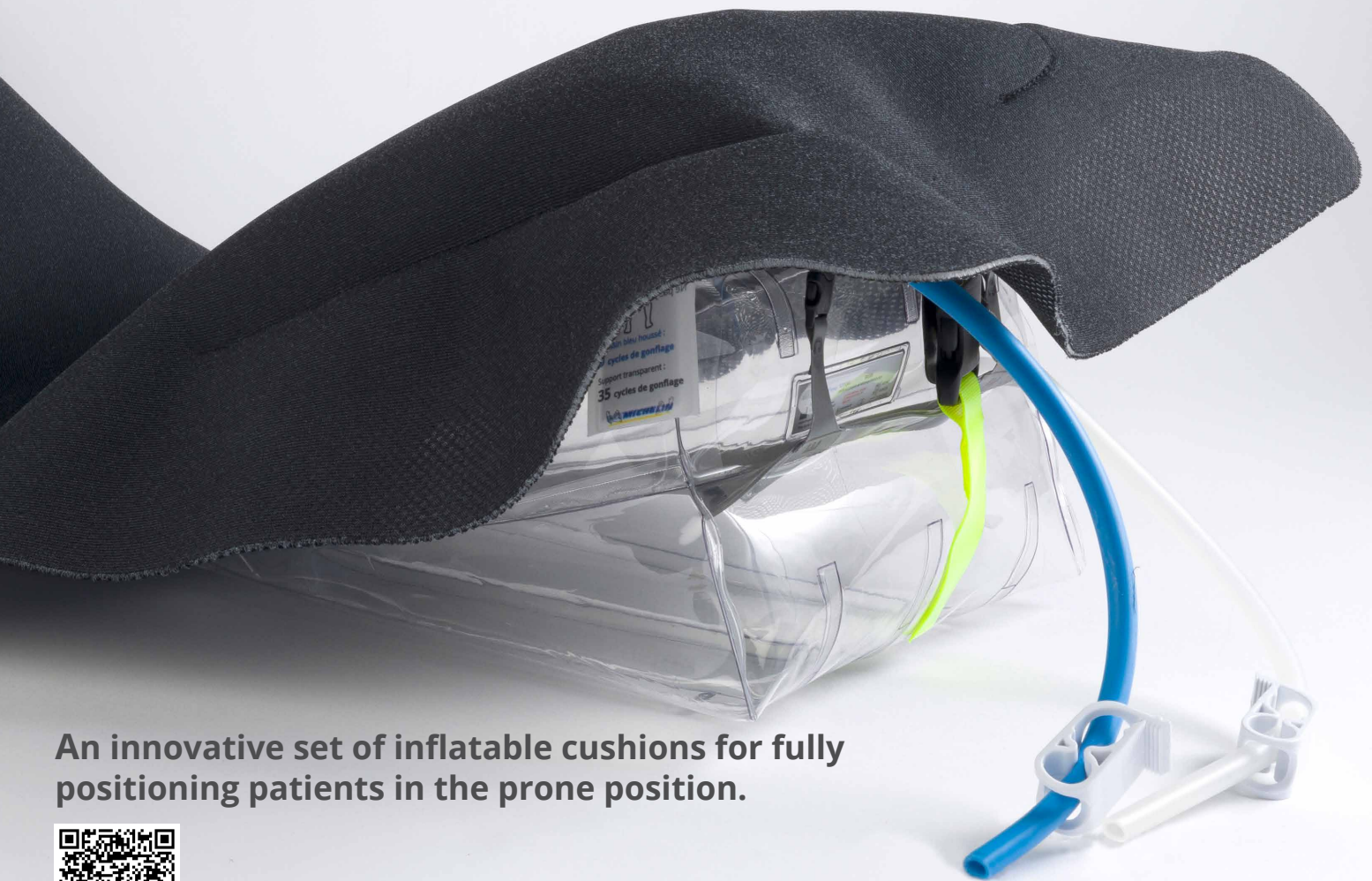


USER MANUAL

MICHELIN AirProne



An innovative set of inflatable cushions for fully positioning patients in the prone position.



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Limited liability company with capital
of €504,000,004.

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European Code: 2211z

MICHELIN AirProne



(photo for information only)

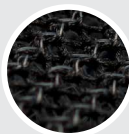
Designation

- Class I medical device in application of Annex VIII of Regulation (EU) No. 2017/745 on medical devices
- CE marking in compliance with the requirements in Regulation (EU) No. 2017/745 on medical devices
- CND Code (medical device nomenclature): Z12011299
- Medical device number: 335399
- Basic UDI-DI No.: 0086699AIRCV

Glossary

- **PP:** Prone position
- **ARDS:** Acute respiratory distress syndrome
- **Inflatable components:** blue cushions and/or clear supports

3D fabric colors



Anthracite gray



White

Manufacturer



**Manufacture Française
Des Pneumatiques Michelin**
Place des Carmes Déchaux
63000 CLERMONT-FERRAND FRANCE

**Single registration number
(SRN-Eudamed):**
FR-MF-000002723

01.

DESCRIPTION OF THE MEDICAL DEVICE

MICHELIN AirProne is a set of inflatable units and covers that enable patients in intensive care units suffering from acute respiratory distress syndrome (ARDS) to be placed in the prone position (PP).

The purpose of this medical device is to reduce the prevalence of pressure ulcers by properly positioning patients.

MICHELIN AirProne is comprised of seven units as shown in Figure A.







MICHELIN AirProne also comes with a spare set of covers.



(photo for information only)

Figure A

CONTENTS

SHIN unit	KNEE unit	ARM unit	PELVIS unit	CHEST unit	HEAD unit
					
<ul style="list-style-type: none"> • Cover • Low-pressure cushion 	<ul style="list-style-type: none"> • Cover • Low-pressure cushion 	<ul style="list-style-type: none"> • Cover • Low-pressure cushion 	<ul style="list-style-type: none"> • Cover • Low-pressure cushion • Clear support • Includes side handles to help reposition the unit if necessary 	<ul style="list-style-type: none"> • Cover • Low-pressure cushion • Clear support 	<ul style="list-style-type: none"> • Cover • Low-pressure cushion • Clear support

Each unit includes a cover and a blue low-pressure cushion. Some units also have a clear support as shown in **Figure B**.



Figure B

- | | | |
|---|--|--|
| <ul style="list-style-type: none"> • Made with 3D fabric to reduce moisture and shearing • Placed over the blue cushion | <ul style="list-style-type: none"> • Reduces contact pressure | <ul style="list-style-type: none"> • Helps position the patient |
|---|--|--|

02. ACCESSORIES FOR THE MEDICAL DEVICE

- *INFLATION SYSTEM*

The units must be inflated with the inflation system provided by Michelin, which is solely intended for use with the MICHELIN AirProne device **Figure C**.

- *WASHING NET*

The covers can be washed in the washing net.

- *CLAMPS*

To stay inflated, the tubes on the inflatable units must be tightened with the clamps.



03. INDICATIONS

- The medical team caring for the patient assumes full responsibility for the use of this medical device.
- This device is intended for placing ARDS patients **with healthy skin only** in the prone position.
- The device is meant to comfortably position the patient and prevent pressure ulcers.

04. CONTRAINDICATIONS

- There are no contraindications for using the MICHELIN AirProne device itself, except that the patient must have healthy skin. Please note that it is not designed for uses other than those cited above.

05. MAXIMUM PATIENT WEIGHT

- This device is recommended for patients weighing up to 250 kg (550 lbs).



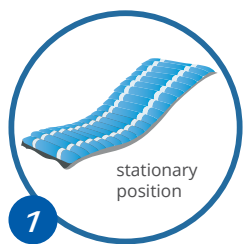
Figure C

06. DIRECTIONS

In order to prevent pressure ulcers, the covers are made out of 3D fabric designed to come in contact with the patient's healthy skin. We do not recommend placing a sheet between the patient and the device.

Below is the suggested sequence of placement, but they may be positioned in a different manner depending on the medical team's standard practices.

HOW TO USE THE MICHELIN AirProne



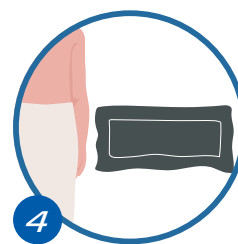
1 Position the bed's alternating pressure mattress to fixed pressure.



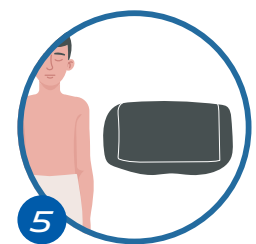
2 Inflate the arm, shin, knee and head units first according to the recommended inflation levels (See §7).



3 Position the patient on their side in line with standard PP procedures.



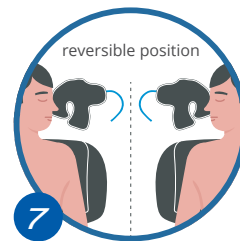
4 Place the deflated pelvic unit facing the patient's pelvis.



5 Place the deflated chest unit facing the patient's chest.



6 Turn the patient on their stomach using the standard PP procedure. Another option is to position the chest unit by lifting the shoulders after turning the patient over.



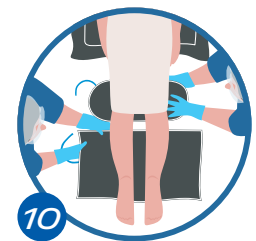
7 Place the head unit facing the patient's head. Be sure to position the ear in the hole made for this purpose.



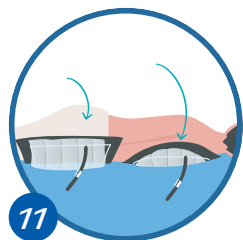
8 Inflate the chest and pelvis units according to the recommended inflation levels (See §7).



9 Inflate/adjust the pressure on the head unit according to the recommended inflation levels (See §7).



10 Position the knee and shin units, then adjust the pressure for the units as needed.



11 Adjust the position and pressure levels, if necessary, of the clear chest and pelvis supports. The patient should be well aligned and not appear bent or arched.

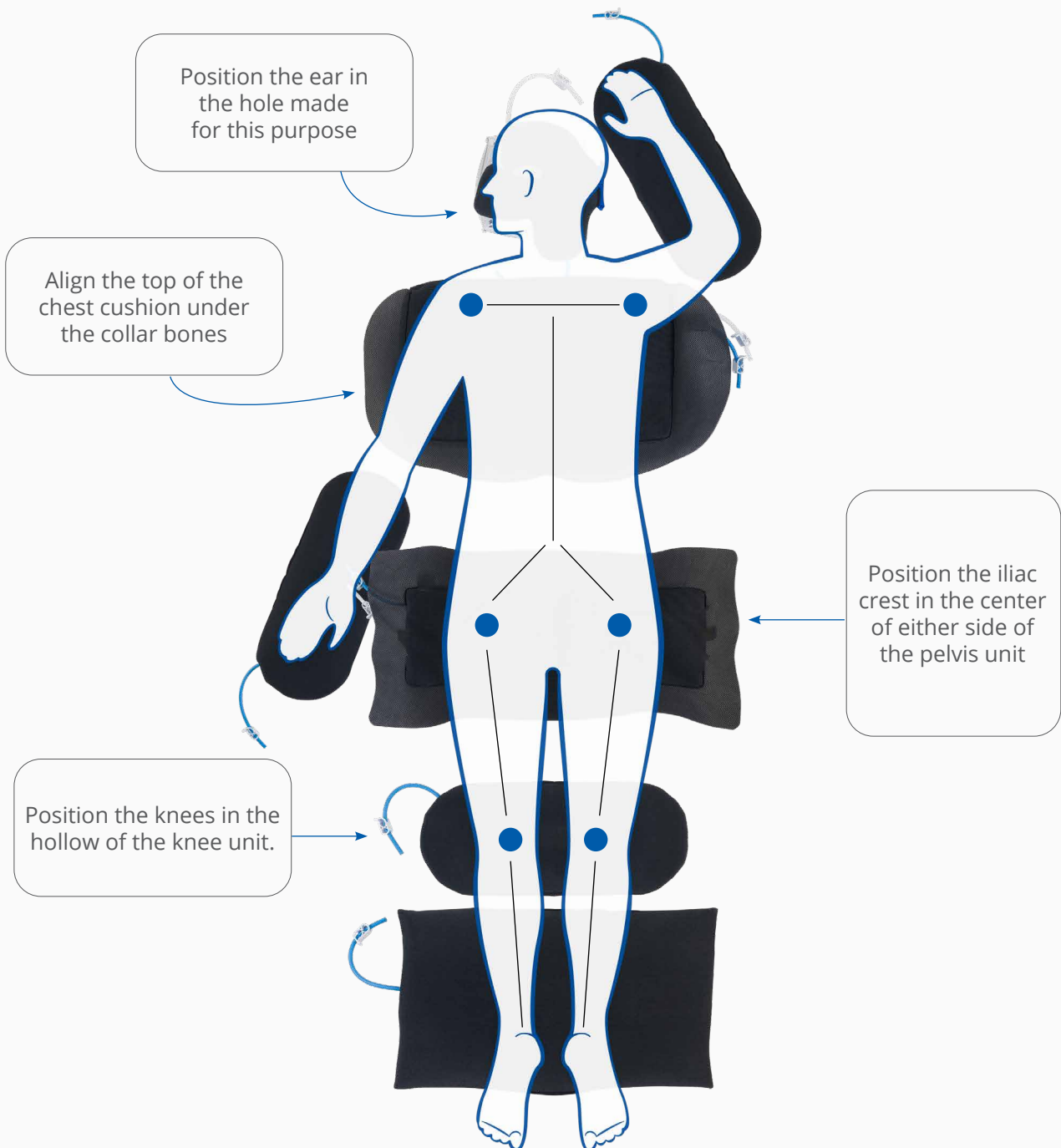


12 Add the arm cushions. They can accommodate a range of regular arm positions in PP.

This device is intended for use with the full set of inflatable units.

If the patient is placed on an inflatable mattress, it must be set in stationary mode to prevent the cushions from moving.

Pay close attention to the points shown in **Figure D**:



(photo for information only)

Figure D

07. RECOMMENDED INFLATION LEVELS

Refer to the table below when inflating the units. It provides the number of inflation pump cycles for a patient who is 1.8 m tall (5'11") and weighs 90 kg (200 lbs). Adjust according to the patient's morphology.

To do a full pump cycle, press the pump all the way

down and then lift up your foot completely, as shown below in **Figure E**.

For best results when inflating, the units must first be fully deflated.

TABLE: RECOMMENDED INFLATION LEVELS

	CUSHION	NUMBER OF INFLATION PUMP CYCLES
HEAD	● Clear support	5
	● Low-pressure cushion	2
CHEST	● Clear support	12
	● Low-pressure cushion	13
PELVIS	● Clear support	35
	● Low-pressure cushion	9
ARM	● Low-pressure cushion	15
KNEE	● Low-pressure cushion	10
SHIN	● Low-pressure cushion	55



(blue cushion)

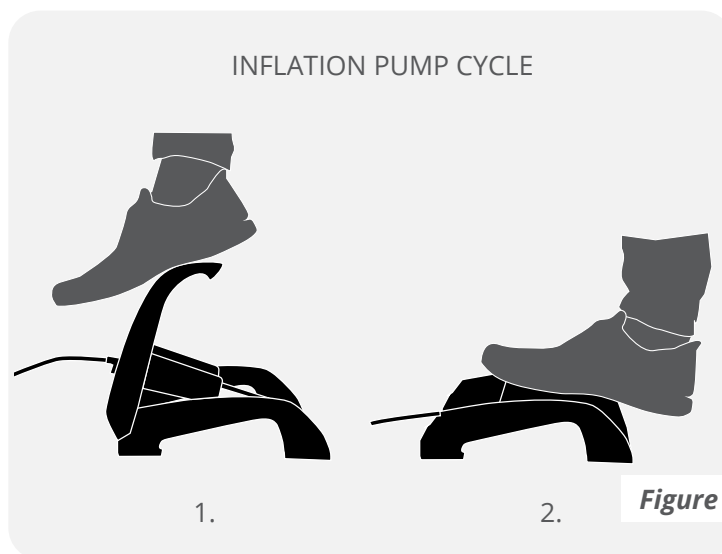


Figure E

Adjust the suggested levels for each unit until they match the descriptions below.



After inflating the blue cushions and placing them under the patient, they should feel soft. They are meant to reduce the prevalence of pressure ulcers.



After inflating the clear supports and placing them under the patient, they should feel firmer than the blue cushions. To suit the patient's morphology, you can adjust them by changing the height of each clear support.

When the patient is properly positioned, their head, shoulders and pelvis look aligned, as shown in **Figure E**:

Alignment of the head, shoulders and pelvis

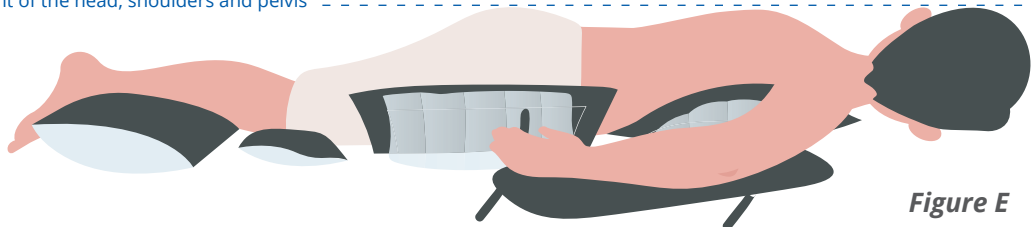


Figure E

08.

WARNINGS AND PRECAUTIONS

- The pelvis and chest units must be properly inflated to ensure the device provides a clinical benefit. Check occasionally to make sure the patient is positioned correctly, and particularly that these two units are well inflated.
- Be especially attentive that the endotracheal tube is well attached to the patient's mouth and that the ventilator line is long enough between the endotracheal tube and the respirator. This will prevent tugging on the tube if the chest or head cushion loses air.
- For the patient's safety, a spare part should be made available either from another device or something that provides the same function like a bolster or foam.
- Once the desired inflation level has been reached, be sure to tighten the clamps on the inflation tubes before disconnecting the pump.
- Keep the units away from sharp objects.
- Failure to follow the directions below on cleaning and disinfecting the units may cause exposure to serious harm and effect the device's lifespan and effectiveness.
- When the head of the bed is elevated, ensure that the angle does not cause the patient to slide.

If a serious incident occurs associated with this medical device, please contact Michelin immediately by emailing: protective@michelin.com

09. CARE AND STORAGE

- Keep this device away from heat, humidity and direct sunlight.
- Keep the units of this medical device away from sharp objects.
- Do not put in contact with corrosive or acidic substances.

10. CLEANING

This device is supplied **in a non-sterile state**.

The cushions and supports should be cleaned and disinfected after use in compliance with local regulations on infectious disease prevention.

Be sure to put the covers back on the units before using them again.

The covers can be removed from the units for cleaning.

To ensure that all bacteria are eliminated and make the covers last as long as possible, we recommend washing them in a washing machine for at least 10 minutes at 60-70°C (140-160°F).

Use detergents recommended for hospitals.

These directions are recommendations from Michelin. They are not replacements for any local regulations or directives. Should any doubts arise, do not hesitate to contact Michelin (protective@michelin.com) or your local infectious disease team.

11. LIMITATIONS OF USE














With regular maintenance, MICHELIN AirProne is a reliable and durable device.

These directions were written to help the user extend the life of the product as much as possible, but they cannot guarantee its lifespan in any way. The user is solely responsible for routinely inspecting the device for any tears, etc. and checking that it is in optimal operating condition.

12. DISPOSAL

When properly maintained, the cushions are sturdy and durable. When they have reached the end of their life, follow the directions on cleaning and disinfecting the device, then dispose of them with non-hazardous hospital waste.

Symbols

	Manufacturer		Non-sterile
	Manufacturing date		Medical device
	Do not expose to moisture		If the packaging is damaged, do not use and read the directions
	Catalog number		Compliant with the requirements in Regulation (EU) No. 2017/745 on medical devices
	Lot number		See the directions on the package insert or website
	Keep out of direct sunlight		Machine washable between 60°C and 70°C
	Attention: for medical use according to the manufacturer's claims		