

## INSTRUCTIONS FOR USE



## VACUUM SPLINTS



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## Thank you for choosing the DEVOLPE`s product

This manual is intended for fulfilling the aim of providing all the information needed so that the client attains excellent use of Vacuum splints and becomes capable of using this device in the most independent and secure way.

**Disclaimer:** Operation instructions and safety precautions are integrated in this document so the suitable and secure use of the product is left to the client's discretion. DEVOLPE takes no responsibility for the troubles caused by improper use of the product. It's highly recommended to provide adequate training in proper use of this product prior to using it in an actual situation. Any medical advice is beyond the limits of this manual.

**Proprietary rights:** The information revealed in this manual is the property of DEVOLPE, Czech Republic. DEVOLPE reserves design and manufacturing rights of this product.

**Conservation of the manual:** This manual must be kept together with the device for the whole life of the product.

**Demolition of the device:** The device can be disposed of as normal solid waste if not contaminated by any dangerous chemicals.

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EN 1865-1:2010-12*

*EN 1789:2007*



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# 1. SAFETY INFORMATION

## 1.1 Warning

- Make sure the instructions belong to the received device. Otherwise, contact the manufacturer immediately.
- Every 6 months, at least, check with us whether there is any update on the user's manual.
- Feel free to contact us in case of any doubt about the accuracy of your interpretation on the instructions.
- Check the functionality of the device on receipt and before every use. Ensure every precaution is taken.
- If you detect any malfunction of the device, immediately remove it from service and contact us or our authorized agency.
- Do not use the device for any purpose other than immobilizing patients.
- Do not keep heavy and/or sharp objects on the device.
- Objects with sharp edges may scratch the lying part of the Vacuum splints. Do not place sharp objects on above said parts.
- Never exceed the load capacity of the device. Determining the load, take into consideration the weight of the patient, the equipment and the accessories.
- Under no circumstances tamper with the device. Any interference could cause malfunctions and dangers for which DEVOLPE takes no responsibility.
- The device must be used by two trained operators. The assistance of qualified staff must also be guaranteed.
- Operators need to have expertise and physical capacity as described in paragraphs 2.1 and 2.2.
- Always use the restraint belts to secure the patient and ensure the belts are fastened correctly.
- Store the device in a cool and dry place in which is not exposed to direct sun.
- If you have to store or transport the device, use its original packaging.
- Keep the device away from any combustion resource.
- Always stay by your patient.
- Maintenance of the device according to this manual is vital to attaining the desired safety.
- Use only DEVOLPE -approved accessories in order to avoid any failure in function of the device, when applicable.



## 1.2 Symbol Glossary

The following symbols are used on the Vacuum splints and in this manual which are recognized by the International Standards Organization:



TRANSFER SHEET LOAD CAPACITY



PLEASE DO NOT EXCEED THE INSTRUCTIONS DURING STORING THE PRODUCT



PLEASE KEEP THE PRODUCT IN THE RIGHT DIRECTION



PLEASE STORE FAR AWAY FIRE OR HAZARDOUS PLACE



PLEASE DO NOT KEEP THE PRODUCT IN THE WET PLACES



PLEASE DO NOT KEEP THE PRODUCT OUT OF THE WAREHOUSE




HAND TRANSPORT

## 1.3 Labels







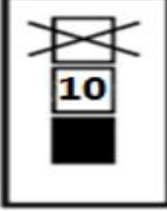


Each device has got labels on it and on its packaging. The labels include information about the product, the model, the company, Lot Number (LN), CE mark (if applicable) and some instructions.


The labels must always be intact and uncovered. Package label is in below:



# DEVOLPE MEDICAL

## CARRYING SHEET

 Fragile handle with care	 This way up	 Keep away from sunlight	 Keep dry	 Keep away from fire
 Stackability	 10 use the trolley	 + 65 °C - 40 °C Storage temperature limit	 Consult instructions for use	




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REF CS/DP

LOT CZR22001CS

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## 2. OPERATOR REQUIREMENTS

### 2.1 Expertise

Vacuum splints is destined for professional use. The rescue operators need to:

have a specialized knowledge of emergency procedures,  
receive training in efficient, effective and safe patient transportation,  
receive training in using this device according to all the information included in this manual,  
take enough of practice before acting in an emergency situation.



**Untrained personnel can cause injury or be injured.**



**READ THE USER'S MANUAL**

**Read the user's manual before any attempt to use the device.**

### 2.2 Physical Capacity

This device demands of participation at least two operators equipped with:

- ability to seize the device firmly with both hands
- strong back, arms and legs for lifting, pushing and pulling
- good muscular coordination



**2 TRAINED OPERATORS REQUIRED**

**Using the Vacuum splints needs at least two specially trained personnel.**

## 3. ABOUT THE VACUUM SPLINTS

### 3.1 Description

A vacuum splint is used as a temporary splint in emergency situations. The thousands of polystyrene beads inside the splint work as an orthopedic cast by molding around the injured limb. The vacuum splint is ideal for stabilizing luxations,





subluxations, and fractures. X-ray, CT, and MRI scans can be performed with the splint in place.

The Multi-Chamber System keeps the internal polystyrene beads in position and eliminates the need for difficult and time consuming manual spreading of the beads. This also enables easy handling, transportation, and storage due to lowest possible weight and size.

 <b>WARNING</b>
Use the Vacuum splints only for the purpose of immobilization.

### 3.2 General specifications

General specifications are rounded to the closest whole number, see table 1. DEVOLPE reserves the right to modify these specifications without any previous notification.

Device`s name	Type	Model	Catalogue code	Lenght (cm)	Width (cm)	Height (cm)	Weight (kg)
Arm Vacuum Splint	Adult	Solo-chamber	VS/03/AVSSDP	67	50/30	3	0.9
Arm Vacuum Splint	Adult	Poli-chamber	VS/04/AVSPDP	67	50/30	3	0.9
Leg Vacuum Splint	Adult	Solo-chamber	VS/01/LVSDP	110	70/40	3	1.8
Leg Vacuum Splint	Adult	Poli-chamber	VS/02/LVSPDP	110	70/40	3	1.8
Ankle Vacuum Splint	Adult	Solo-chamber	VS/05/ANVSSDP	57	47	3	0.9
Ankle Vacuum Splint	Adult	Poli-chamber	VS/06/ANVSPDP	57	47	3	0.9



Head Vacuum Splint	Adult	Poli-chamber	VS/07/HVSDP	31	38	8	0.7
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Table. 1

### 3.3 Components

1	Lying part
2	Handles
3	Safety belts



Key. 1

*\*Note: Product is available with its carrying bag which is integral part sold together with the product.*

### 3.4 Accessories

- Vacuum pump
- Carrying bag



## 4. OPERATING INSTRUCTIONS

### 4.1 Storage and Transportation

Before transportation, make sure the device is suitably packaged ensuring there is no risk of damage.





Keep the original packaging for future storage or transportation. Damage or puncture to the device during transportation is not covered by guarantee.

## 4.2 Preparation

On receipt of the product:

- Remove the packaging and make sure that all components are visible.
- Assure all the components are present.

The device must be checked before every use so any abnormality is revealed. Follow the maintenance instructions in this manual to make sure you are in careful preparation.

Please make sure that lying part is free of cuts, punctures, otherwise contact the Authorized person/agency immediately.

## 4.3 Using the Vacuum splints

### 4.3.1 Preparing the Vacuum splints for the Patient

- Determine the location of the fracture,
- Manually stabilize the bone,
- Hand off the manual stabilization to your partner if needed.


### 4.3.2 Using the Vacuum splints on injured place

- Assess the PMS,
- Remove the cap from the valve,
- Make the device pliable,
- Smooth out the device by hand to form a level surface,
- Connect the pump to the device,
- Evacuate air until the device is semi-rigid,
- Position the splint in place, making sure to splint the joints above and below the fracture,
- Open the valve allowing air to enter. Keep the valve open until the device softens and conforms to the shape of the arm/leg.
- Shape the device around the arm/leg/head,
- Secure the device to the patient's arm/leg by fastening the straps. However, do not pull the straps too tightly,
- Use the valve and the deflation pump for air evacuation. Evacuate until the desired firmness is achieved,



### 4.3.3 Using the device with a spinal board

- Move the patient to a long spinal board,
- Strap the patient to the board,
- Reassess the PMS.

 <b>WARNING</b>
<b>Do not close the valve until the Vacuum splint is fully immobilized.</b>

## 5. MAINTENANCE

### 5.1 Storage

Store the device in a cool and dry place away from direct sun and damaging chemical substances. Always store it after cleaning (and disinfection, when applicable) and prepare for the next use.

### 5.2 Schedule

Maintenance must include cleaning, disinfecting and inspecting. Minimum interval for each procedure is a must and indicated in table 2.

OPERATION	cleaning	disinfecting	inspecting
Min. Intervals	20 mins after each use	30 mins after each use	Before each usage

Table. 2

Plan and follow a maintenance schedule. Maintain maintenance records. A sample record table is provided here, see table 3.

Maintenance Date	Operation	Result	Performed By

Table. 3



### 5.3 Cleaning

Cleaning the Vacuum splints:

1. Clean all the surfaces with warm water, a not strong detergent (soap at some occasions) and your hand.
2. Rinse the Vacuum splints with clear, warm water.
3. Dry the Vacuum splints with a soft, clean towel or leave it for air-drying.

#### WARNING

**Do not use cleaners containing bleach or iodine. These chemicals can cause damage.**

#### WARNING

**Do not use abrasive cleaning compounds or applicators. Abrasive materials can result in damage.**

#### WARNING

**Do not clean with high pressure water. It can damage the joints and cause gradual destruction.**

#### WARNING

**Do not clean the device with a sharp thing. Sharp things can tear the device.**

### 5.4 Disinfecting

We must note that we are not specialist in disinfecting techniques. All we can do is to recommend finding a proper disinfectant and follow the manufacturer's instructions. It's very important to know how to apply the chemicals properly.

#### WARNING



**Failure of cleaning or disinfecting increases the risk of cross infection.**

### 5.5 Inspecting

Trained personnel must inspect the Vacuum splints for damages or malfunctions regularly. We have provided you with an inspection checklist to help you make sure every precaution is taken, see table 4.

INSPECTION CHECKLIST
<ul style="list-style-type: none"> <li>✓ <i>Is Are all the components in place?</i></li> <li>✓ <i>Is the device free of damage?</i></li> <li>✓ <i>Does the valve function properly?</i></li> <li>✓ <i>Do the buckles function properly?</i></li> <li>✓ <i>Are the straps intact?</i></li> <li>✓ <i>Does the pump function properly?</i></li> </ul>

Table. 4

Remove the Vacuum splints from service in case of any concerns and contact the authorized agency.

## 6. LIMITED WARRANTY STATEMENT

DEVOLPE products are under two-year warranty reckoned from the date of invoice issuance. Warranty does not include if:

- the device fails to work due to usage not in accordance with the instructions written in the current document.
- the device is damaged by accident or natural hazards.
- lacks serial number or other important labels, if applicable.
- the device is repaired by unauthorized person/agency.

DEVOLPE does not take responsibility for the costs and risks of device's transportation back and forth if the purchaser is not located in Czech Republic, Turkey or any authorized agency's district.

## 7. AFTER-SALES SERVICE

DEVOLPE offers after-sales services for its products under the conditions stated in agreements with customers.

\*Note: Contact the Manufacturer for more information.

