

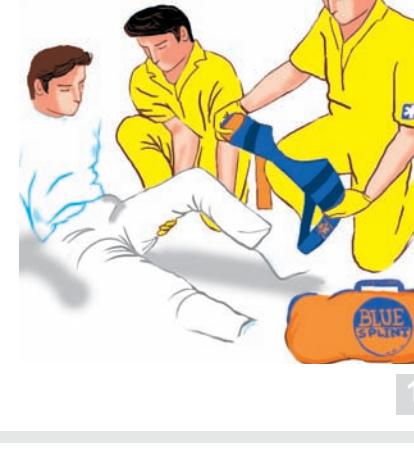


SPENCER®

Rigid splints with flexible internal structure Stecchobende rigide con anima flessibile

Manually immobilise the injured limb in either the analgesic position or maintaining the patient's position. Prepare a Blue Splint/Blue Splint Pro which is the correct size for the limb (it must cover both the articulation above and below the fractured bone). Bend and adapt the metal bar inside to follow the morphology of the injured limb.

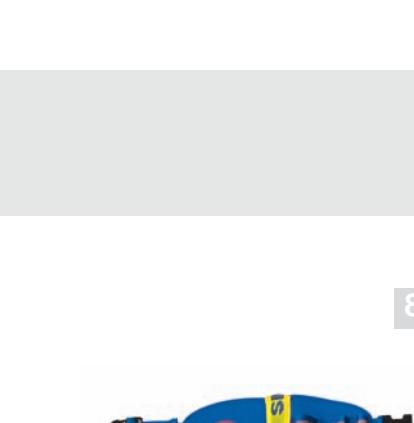
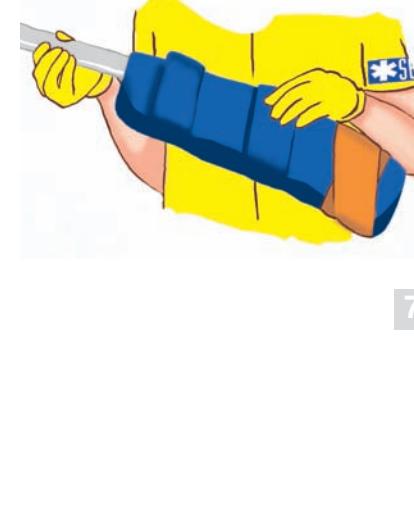
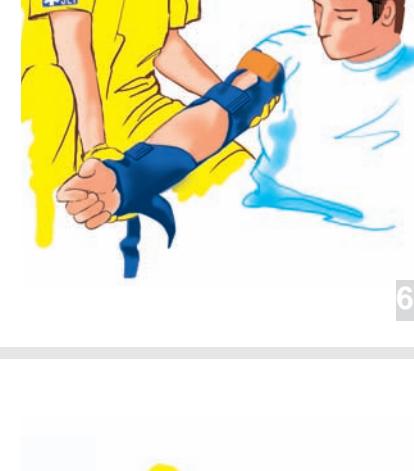
Immobilizzare l'arto lesso manualmente, nella posizione antalgica o nella posizione di reperimento. Preparare la Blue Splint/Blue Splint Pro della misura idonea all'arto (deve comprendere le articolazioni a valle e a monte dell'osso fratturato). Piegar la barra metallica interna adattandola alla morfologia dell'arto.



Férulas rígidas con alma flexible Attelles rigides avec armature modelable

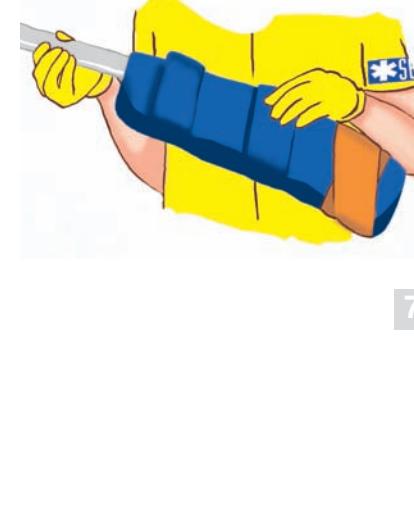
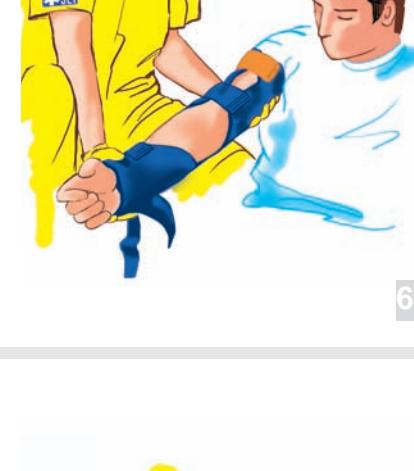
Inmovilizar el miembro herido manualmente, en la posición antiálgica o en la posición de localización. Preparar la Blue Splint/Blue Splint Pro con la medida ajustada al miembro (debe incluir desde principio a fin el hueso fracturado). Plegar la varilla metálica interna adaptandola a la morfología del miembro.

Immobiliser manuellement le membre fracturé, en position antalgique ou en position dans laquelle se trouve le membre. Utiliser la Blue Splint/Blue Splint Pro de la taille adéquate au membre (doit inclure desde principio a fin el hueso fracturado). Plier la tige métallique intérieure qui se trouve à l'intérieur de l'attelle l'adaptant à la morphologie du membre.



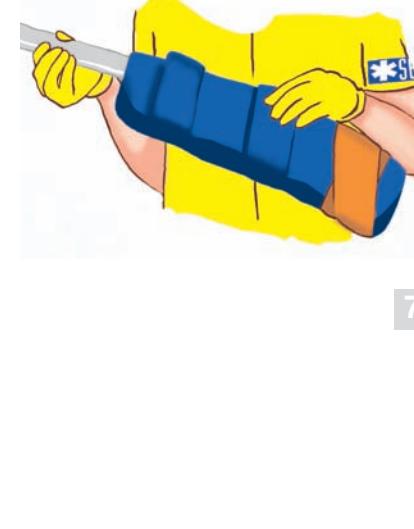
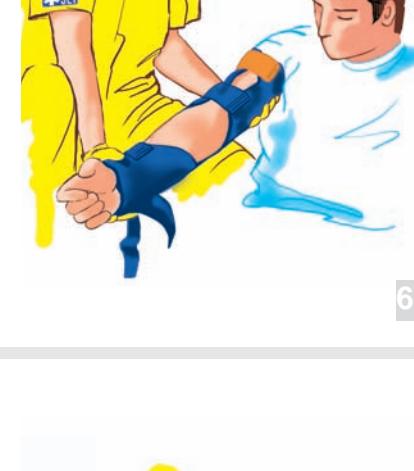
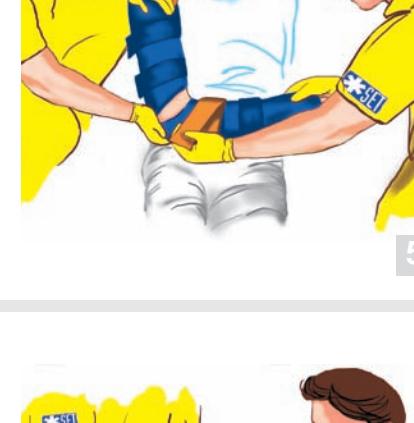
Aplicar delicadamente la férula, manteniendo la varilla metálica interna abajo del miembro. Cerrar las fijaciones de Velcro® o las hebillas plásticas comenzando por la parte distal y asegurando que no se comprima el punto herido.

Appliquer délicatement l'attelle, en gardant la tige métallique intérieure en dessous du membre. Fermer les bandes en Velcro® ou les boucles plastiques en partant de la portion distale en vérifiant de ne pas comprimer le point fracturé.



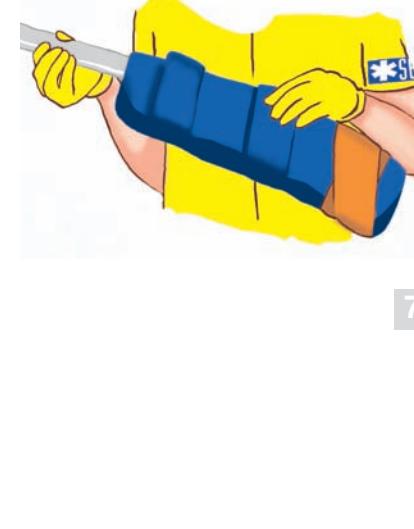
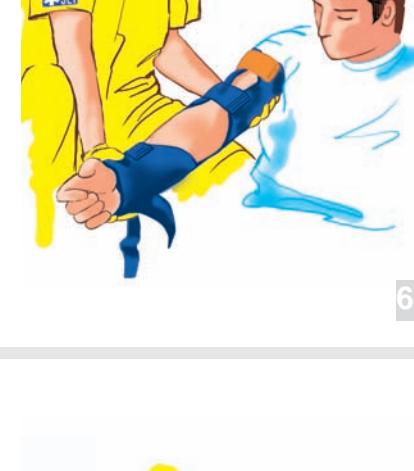
Proceder de la misma manera tanto para la inmovilización del miembro inferior como para el superior.

Procéder de la même façon pour l'immobilisation du membre inférieur, et du membre supérieur.



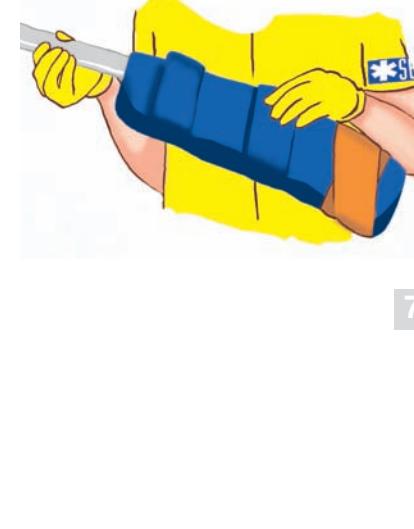
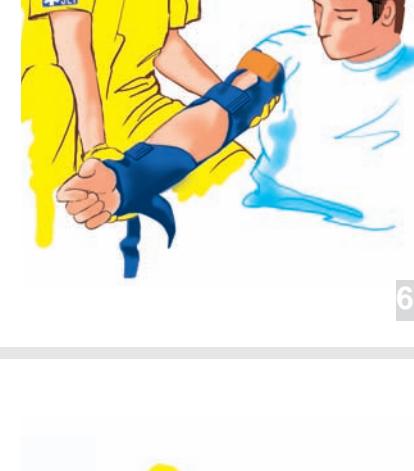
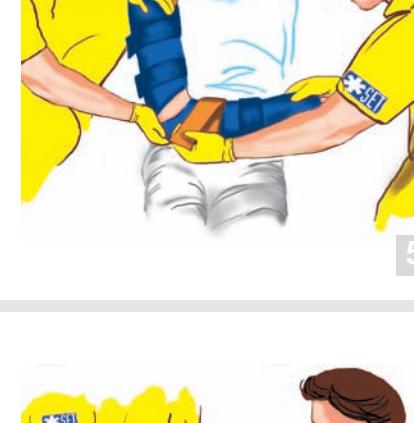
Aplicar distintas Blue Splint/Blue Splint Pro sobre el mismo miembro contemporaneamente para aumentar la inmovilización y extender el efecto.

Appliquer simultanément plusieurs Blue Splint/Blue Splint Pro sur le même membre pour augmenter l'immobilisation et multiplier l'effet.



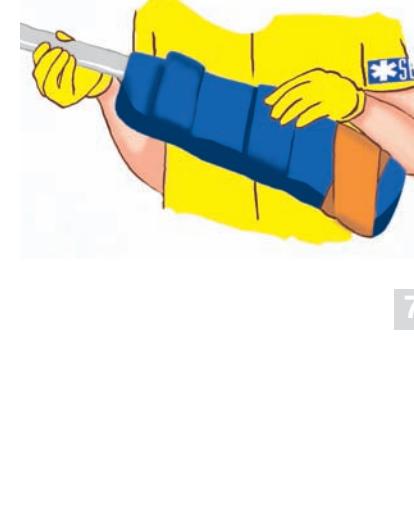
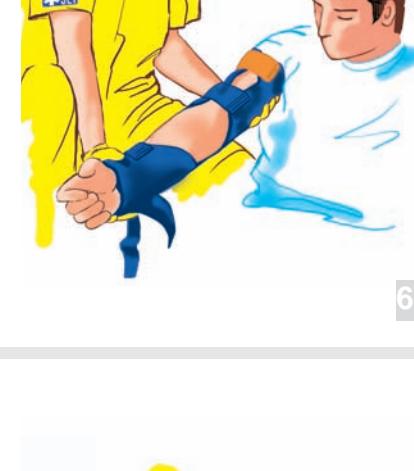
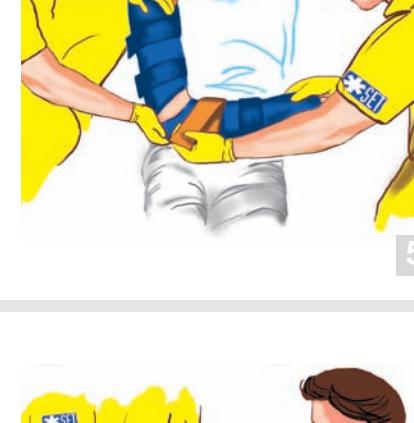
Las Blue Splint/Blue Splint Pro son muy ligeras y se pueden sobreponer las unas a las otras creando una infinitud de configuraciones y soluciones. Pueden usarse en adultos y niños de todas las tallas.

Les Blue Splint/Blue Splint Pro sont extrêmement légères et peuvent se positionner l'une sur l'autre en créant une infinité de configurations et solutions. Elles peuvent être utilisées chez l'adulte et chez l'enfant.



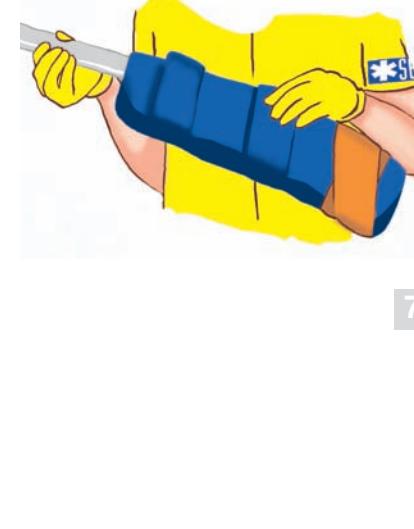
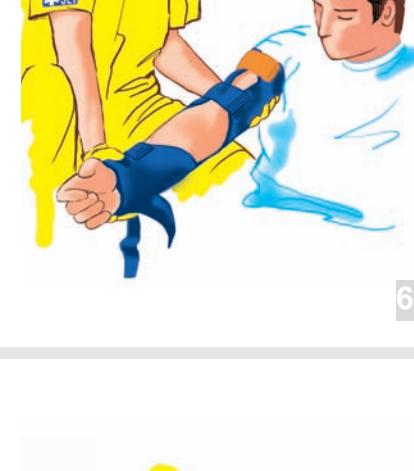
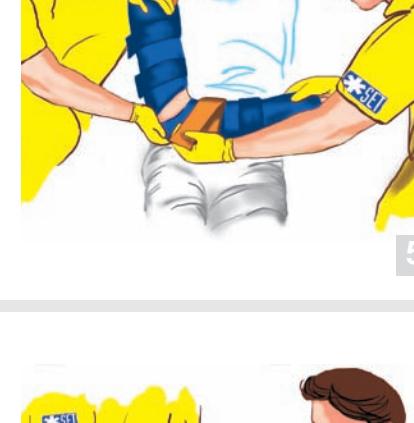
La férula para codo/tobillo/rodilla puede ser utilizada incluso como inmovilizador de brazo durante las infusiones venosas.

L'attelle pour le bras ou l'avant-bras peut être aussi utilisée comme accoudoir pour perfusions.

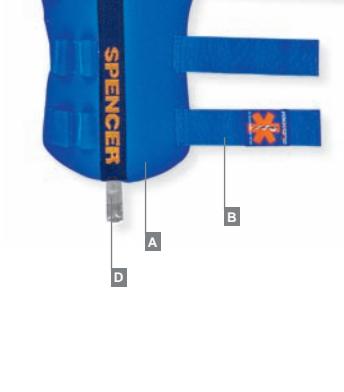


Las ferulas se pueden limpiar con alcohol o desinfectantes neutros. Quitando el alma interna, se pueden lavar en lavadora. Para las Blue Splint Pro, enganchar las dos partes de las hebillas macho y hembra para proceder al lavado en lavadora.

Le nettoyage peut se faire à froid avec de l'alcool ou d'autres désinfectants neutres. En retirant l'âme métallique les attelles peuvent se laver à la machine à laver. Pour les Blue Splint Pro, vérifier que les boucles plastiques soient fermées.



Main components Componenti principali



Componentes principales Pièces principales



User's Manual

This appliance conforms with the Directive 93/42/CEE "Medical Devices".
Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV Product Service GmbH.

1 GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction manual

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 Symbols used

General or specific warning

See instructions for use

Lot number

Product code

Product compliant with specifications of the Directive 93/42/CEE

1.4 Servicing request

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 Demolition

Follow the current regulations.

1.6 Labelling

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) on the label.

2 WARNINGS

2.1 General warnings

* Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.

* In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.

* Regularly check the appliance.

* In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.

* Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or resuer.

* The appliance must not in any way be tampered with. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself.

* Those who modify or have modified, prepared or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.

* Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.

* Handle with care.

2.2 Specific warnings

* The product must be used by trained personnel only.

* If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.

* When the device is being used, the assistance of qualified staff must be guaranteed.

* The splint must be applied by at least two trained operators, with good practical sense and common sense.

* Before modelling the splint, evaluate the application in relation to the visibility of wounds or fractures.

* The device should not be exposed nor get in contact with heat sources or flammable agents.

* Use the device only as described in this manual.

* Always check the integrity of all the parts of the device before use.

2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3 PRODUCT DESCRIPTION

3.1 Intended use

Blue/Splint/Blue/Splint Pro are flexible splints designed to immobilise dislocated or sprained limbs. They can be adapted to the various positions indicated for the pathology and are quick to apply. They are not bulky once applied and they do not increase the patient's inertial mass. Their flexibility is due to the possibility of shaping the metal core inside the Blue/Splint/Blue/Splint Pro in order to adapt it to the shape of the limb to immobilize in order to position the limb in a reliable manner for stability during transport. Each splint can therefore be adapted to the fracture type and the rescuer does not have to bother to reduce the dimensions. This permits transport of injured limbs in angled pathological position which will guarantee the correct limitation of movement in all directions. The closures in Velcro® (for Blue/Splint) or with the rapid adjustment and closure system (Blue/Splint Pro) are quick to apply and are easily adapted to the various patient sizes. Use of the various sizes offers the possibility to immobilise multiple fractures. Stored in their special transport bag, or applied to the patient, the Blue/Splint/Blue/Splint Pro are characterised by their particularly reduced volume which makes them ideal for any type of operation in any condition. The patient cannot intervene on the device in any way.

3.2 Main components (fig. 8)

A Nyprene structure (the outside part is blue, the inside is black)

B Velcro® closures (the orange webbing highlights the top part, the blue webbing is used for the other points)

C Quick-release and regulation closures (nylon webbing with integrated regulator)

D Flexible inside structure made of a tempered ergal profile

E Ripstop carrying case

3.3 Models

JM80003A Blue Splint leg

JM80004A Blue Splint arm

JM80005A Blue Splint forearm

JM80006A Blue Splint wrist

JM80007A Blue Splint elbow/ankle

JM80002A Blue Splint Kit 5 sizes with bag

JM80030A Blue Splint Pro leg

JM80031A Blue Splint Pro arm

JM80032A Blue Splint Pro forearm

JM80033A Blue Splint Pro wrist

JM80034A Blue Splint Pro elbow/ankle

JM80035A Blue Splint Pro Kit 5 sizes with bag

3.4 Technical data

Dimensions Blue/Splint/Blue/Splint Pro leg: 578 x 420 mm

Dimensions Blue/Splint/Blue/Splint Pro arm: 582 x 290 mm

Dimensions Blue/Splint/Blue/Splint Pro forearm: 387 x 300 mm

Dimensions Blue/Splint/Blue/Splint Pro wrist: 302 x 255 mm

Dimensions Blue/Splint/Blue/Splint Pro elbow/ankle: 540 x 305 mm

Dimensions Blue/Splint/Blue/Splint Pro Kit: 640 x 100 x h310 mm

Weight Blue/Splint/Blue/Splint Pro Kit: 680 x 80 x h350 mm

Weight Blue/Splint/Blue/Splint Pro Kit: 1.5 kg

Functioning temperature: from -40 to +60 °C

Storage temperature: from -40 to +86 °C

Relative humidity: from 30 to 75%

Blue/Splint/Blue/Splint Pro are manufactured in a material which permits excellent thermal isolation of the immobilised limb and they permit the application of localised pressure on the fixing points. The use of Velcro® (or of the rapid adjustment and attachment system) with the elastic properties of the Nyprene material permit complete control of compression aided by the elastic properties of the material. All materials used are long lasting and 100% impermeable.

4 OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packed ensuring also that there are no risks of shocks, bumps or falls during the transport itself. Keep the original packaging for use in case of any further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The appliance must be stored in a dry place free from humidity.

4.3 Functioning

See back.

4.4 Troubleshooting

Problem

1. Closure is insufficient

2. The metal core inside has lost its functional characteristics

Cause

1. Closing system is worn out

2. Wear and tear

Remedy

1-2. Put immediately the device out of service and contact the service centre

5 MAINTENANCE AND CLEANING

5.1 Cleaning

Can be carried out using alcohol or other neutral disinfectants. If the metal core is removed, they can be machine washed at the maximum temperature of 40 °C. The straps of the Blue/Splint Pro model must be closed before machine washing.

5.2 Maintenance

The person responsible for every day maintenance can only substitute the spare parts indicated on paragraph 6.2 "Spare Parts". All other substitutions or repairs can be carried out only by the manufacturer or by a centre authorised by the manufacturer.

The device does not require programmed servicing.

5.2.2 Special servicing
Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations. For any operations that are not carried out directly by the manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device. The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer.

6 ACCESSORIES AND SPARE PARTS

6.1 Accessories

JM80008A Ripstop carrying case

6.2 Spare parts

JM80014A Metal profile for arm splint

JM80015A Metal profile for forearm splint

JM80016A Metal profile for wrist splint

JM80017A Metal profile for elbow/ankle splint

JM80018A Metal profile for leg splint

Manuale d'Uso e Manutenzione

Sì dichiara che il dispositivo è conforme alla Direttiva 93/42/CEE "Dispositivi Medici".

Sistema di Garanzia di Qualità per la produzione ed il controllo finale dei prodotti certificato dall'organismo notificato TÜV Product Service GmbH.

1 INFORMAZIONI GENERALI

1.1 Scopo e contenuto

Questo manuale d'uso ha lo scopo di fornire al cliente tutte le informazioni necessarie affinché, oltre ad utilizzare adeguatamente il dispositivo, sia in grado di gestire lo strumento nel modo più autonomo e sicuro possibile. Esso comprende informazioni inerenti l'aspetto tecnico, il funzionamento, la manutenzione, i ricambi e la sicurezza.

1.2 Conservazione del manuale d'uso

Il manuale d'uso e manutenzione deve essere conservato nelle vicinanze del prodotto, all'interno di un apposito contenitore e soprattutto al riparo da qualsiasi elemento o sostanza che ne possa compromettere la perfetta leggibilità.

1.3 Simboli utilizzati



Avvertenze generali e/o specifiche



Consultare istruzioni d'uso



Numero di lotto



Codice identificativo del prodotto



Prodotto conforme ai requisiti previsti nella Direttiva 93/42/CEE



Advertencias generales y/o específicas



Consultar el manual del usuario



Número de lote



Código identificativo del producto



Producto conforme a los requisitos previstos en la Directiva 93/42/CEE



Instructioins générales et/ou spécifiques



Consulter la notice d'utilisation



Numéro de lot



Référence du produit



Produit conforme aux standards de la Directive 93/42/CEE

Manual de Uso y Manutención

Se declara que el dispositivo es conforme a la Directiva 93/42/CEE "Dispositivos Médicos".

Sistema de Garantía de Calidad para la producción y el control final de los productos certificado por el organismo notificado TÜV Product Service GmbH.