ZEPHYR

Patient Transport Sled

Users Manual

DIACOR

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This manual contains the latest information at the time of publication. Diacor, Inc. reserves the right to revise this manual without notice.

WARNING

The Zephyr Patient Transport Sled is intended for use only by physicians qualified in diagnostic imaging or radiation oncology and experienced in gynecologic or prostate cancer planning or treatment, or by therapists at the specific direction of such qualified physicians. It is the sole responsibility of the physician to judge whether the use of the Zephyr Patient Transport Sled is clinically appropriate, whether the initial treatment plan is adequate to achieve his or her clinical goals and whether the treatments are administered as prescribed.

Diacor, Inc. has appointed M. Devices Group as our EU Authorized Representative. Contact Information: M. Devices Group, Marlborough House, Riding Street, Southport, PR8 1EW, United Kingdom, Tel: +44 1704 544 944, Fax: +44 1704 544 050

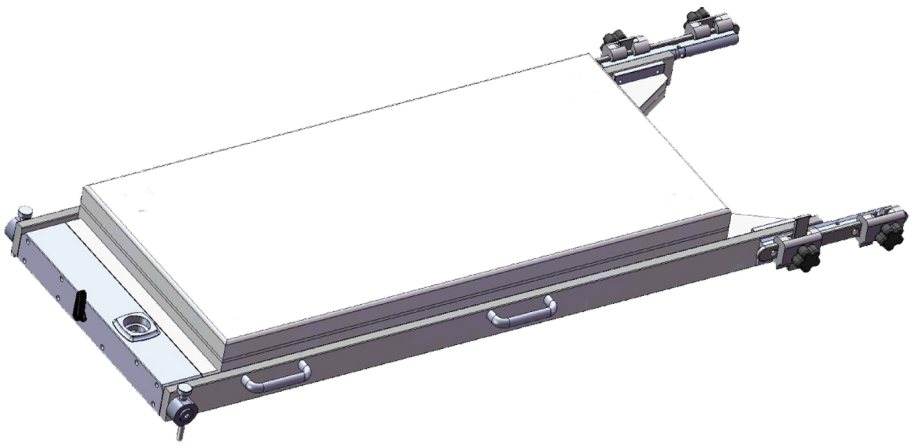

Figure 1.1 Diacor Zephyr Patient Transport Sled

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SECTION 1

INTRODUCTION

The Diacor Zephyr™ Patient Transport Sled with accessories provides the immobilization and positioning capability to easily move a patient along a flat surface to a position best suited for diagnostic imaging. The patient's position remains unchanged during the movement of the patient.

The two basic components of the Patient Transport Sled are the sled itself with foam pads and the air blower with its connecting hose. The sled rests on a flat surface and the patient rests on the sled pads. The air blower is turned on and the patient and sled are lifted a small fraction of an inch above the flat surface under a pillow of air. The attending therapists are then able to slide the sled and patient to a position where an acceptable image can be taken of the patient. The air blower is turned off and the sled slowly settles on the flat supporting surface.

As an example of the use of the Patient Transport Sled occurs when a patient requires brachytherapy implants and treatment. The implant may be done at the end of a flat surface like a CT flat table top. The positions of the implants are verified by sliding the patient on the sled to a position on the flat table top that can be scanned. While the patient's position has changed, the motion does not cause the implants to move within the patient.

SECTION 2

GENERAL DESCRIPTION

2.1 GENERAL

This section contains a brief description of the features and physical characteristics of the Diacor Zephyr Patient Transport Sled, blower and air hose.

2.2 FEATURES

Figures 2.1 and Figure 2.2 show the transport sled with pointers to the various features of the device.

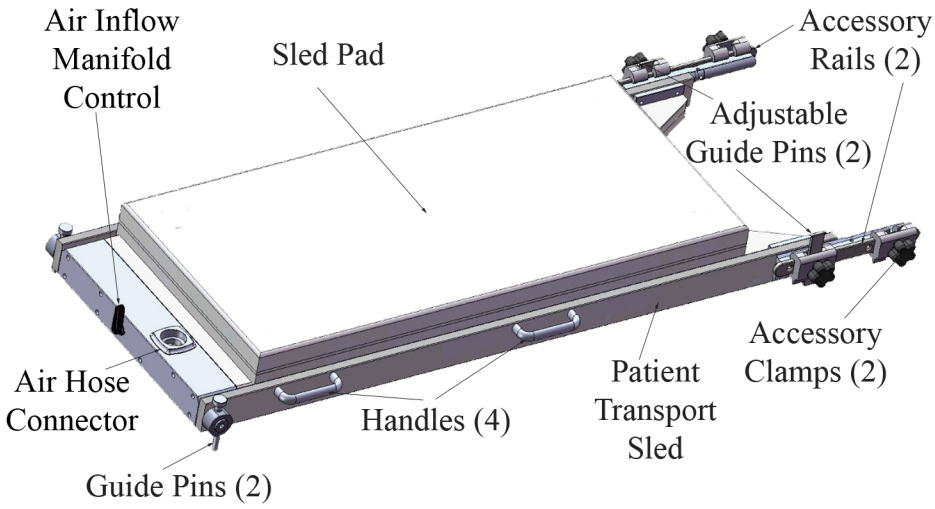

Figure 2.1 Zephyr Sled Features

2.2.1 Patient Transport Sled

The Patient Transport Sled is constructed from polyvinyl chloride (PVC) plastic. Handles are provided to help the user move the sled to and from a flat surface such as a CT flat table top. Guide pins are provided to keep the sled on the CT flat table top. Accessory attachment bars are provided to allow stirrups or other necessary attachments to be connected to the sled. The sled provides a connection for an air hose and air flow manifold to control the distribution of air between the head end and the foot end of the sled when there is air flow to the sled.

2.2.1.1 Sled Pad

Pads are provided for the patients comfort. They are held in place with Velcro® strips and can be removed to clean or reposition.

2.2.1.2 Air Hose Connector

The hose connector accepts the mating connector on the air hose. To attach the hose, it is only necessary to twist hose connector a partial turn to lock the hose to the sled.

2.2.1.3 Air Inflow Manifold and Control

The air inflow manifold directs the incoming air to the three air pillows. There is a control lever on the manifold to adjust the amount of air going to the air pillows. In the case of heavy patients, the foot end of the sled may drag. In this case, air flow can be restricted to the head end to provide maximum lift to the foot end of the sled.

2.2.1.4 Guide Pins

Four adjustable guide pins help keep the sled on the CT flat table top (FTT) as the user guides the sled and patient along the length of the CT FTT. A pull release allows two of the pins to be locked in a down position where the pins slide against the side of the FTT or in a horizontal position to allow the sled to be easily moved from the FTT. There are three different lengths of these guide pins. The set of pins installed should allow the pins to slide along the sides of the FTT without catching on the shroud of the table. The second pair of guides are vertically adjustable by releasing the clamp handle, adjusting the guide to a desired length and then retightening the clamp handle.

2.2.1.5 Handles

Four handles allow the user to lift the sled to and from the FTT. They also provide a hand hold for the user to grasp as they move the sled and patient along the surface of the FTT.

2.2.1.6 Accessory Rails

Two accessory rails are provided on each side of the sled. These bars are designed to accept typical accessory clamps found on diagnostic and other tables that require accessory attachment. Accessories like stirrups are inserted and locked into the clamps on the accessory rails. The length of the accessory bars allows more than one accessory to be attached at the same time.

2.2.1.7 Sled Shape

The sled shape at the foot end of the table allows the physician close access to the patient. This allows the insertion of implants with minimum interference from the sled.

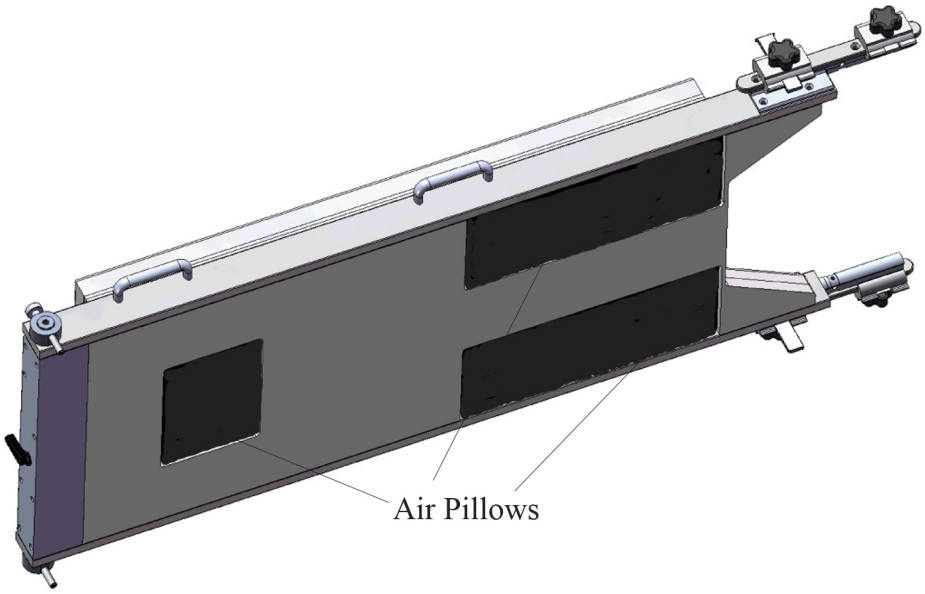

Figure 2.2 Bottom View of Zephyr Patient Transport Sled

2.2.1.8 Air Pillows

Figure 2.2 shows the three air pillows that support the sled and the patient when air is supplied to the sled.

Figure 2.3 Zephyr Air Blower and Hose

2.2.2 Air Blower and Hose

The air blower and hose connect to the patient transfer sled. When the air is turned on, the air escapes by passing through small holes in the air pillows. The air pressure contained in the pillows lifts the sled and patient so they can be moved very easily. The blower has an internal filter that needs to be replaced periodically. Figure 2.3 shows the air blower and hose as well as important features of the blower.

2.2.2.1 Power Cord/Handheld Blower Control

The power cord is a hospital grade cable and plug that provides power to the blower when it is plugged into a power outlet. The Handheld Blower Control provides the user with the ability to turn power to the blower on and off and to adjust the amount of power to the blower to control the lift of the sled and patient. The Handheld Blower Control includes three components, a power cord and plug, a power control box and a handheld power switch and variable power control attached at the end of a long cord. The handheld power switch has red LED indicator that illuminates when the switch is turned on and power is applied to the blower.

2.2.2.2 ON/OFF Switch

The ON/OFF switch is a push to connect/push to disconnect power switch. The switch must be in the ON position to enable the Handheld Blower Control to control the power to the blower.

2.2.2.3 Flexible Hose

A flexible hose carries the air from the air blower to the sled. A ten (10) foot hose is supplied with the Zephyr Patient Transport Sled.

2.2.2.4 Quick Turn Hose Connection

A quick turn connector attached to each end of the flexible hose connects to both the air blower and the sled.

SECTION 3

ACCESSORIES

3.1 GENERAL

The Zephyr Patient Transport Sled includes one accessory. It is a set of lithotomy stirrups shown clamped to side rails in Figure 3.1.

Figure 3.1 Lithotomy Stirrups

3.2 FEATURES

These stirrups represent the gold standard in lithotomy positioning. They allow for easy adjustment of abduction and lithotomy while maintaining the sterile field. The boot design reduces pressure under the popliteal fossa and the superficial peroneal nerve. The stirrups enables safe and easy positioning while providing enhanced surgical site access.

- **Boot Design** - Helps reduce pressure under the popliteal fossa and superficial peroneal nerve.

- **Floating Boot** - Self-adjusting boot minimizes pressure on the calf when moving the stirrup.

- **Lift-Assist** - Allows easy movement of the leg when placing it in the desired position.

- **Twist Release Grip Handle** - Provides easy intra-operative adjustment without compromising the sterile field. Simply twist the handle to secure the leg holder in all directions.

- **Lithotomy Range** - Set the stirrup in any position between +90° to -35° lithotomy.

- **Abduction Range** - Set the stirrup in any position between +25° to -9° abduction.

- **Lithotomy & Length Indicators** - Visual indicators that help ensure precise positioning.

Detailed instructions for use of the stirrups are found in the stirrup user manual. This manual is included in the package of user information provided with the Zephyr Patient Transport Sled.

SECTION 4

UNPACKING, INSTALLATION, USE

4.1 GENERAL

The Diacor Zephyr Patient Transport Sled is designed ready for use following removal from its packing container.

4.2 UNPACKING AND INSPECTION

When the Zephyr Patient Transport Sled arrives, inspect all shipping containers for evidence of physical damage. If there are any dents, scratches or other evidence of physical damage to the boxes, note the damage on the shipper's copy of the bill of lading and file a claim against the shipper.

In the case of shortages or malfunctions, notify Diacor immediately to arrange for replacement or repair. Refer to sections 6.3 for the discussion of replacement or repair of products under warranty. Save all packing containers and materials for the Zephyr Patient Transport Sled in case it needs to be returned to Diacor for replacement or repair.

4.3 INSTALLATION

The Zephyr Patient Transport Sled is shipped ready to use. The sled must be placed on a CT flat table top (FTT). The sled is heavy and two people should lift the sled. The cutout section of the sled should be at the foot end of the CT FTT. The three air pillows should be resting on the surface of the FTT.

The air hose must be connected to both the connector on the sled as well as the connector on the air blower. The electrical cord from the air blower must be inserted into an AC power outlet.

Each of the four guide pins should be adjusted so that the guide pin on each guide is pointing toward the floor. At the head end of the sled, lift the guide pin handle to unlock the pin and then rotate until the locking pin seats with the pin in a vertical position. At the foot end of the sled, adjust the length of the guide pin by loosening and then tightening the guide pin clamp. These four guide pins should be moved to a horizontal position or adjusted to be above the base of the sled whenever the sled is moved to or from the CT FTT. Lift the guide pin handle to unlock the pin and then rotate until the locking pin seats with the pin in a horizontal position. Loosen the guide pin clamp, lift the guide pin to clear the lower edge of the sled and then tighten the guide pin clamp.

The stirrups clamps are installed on the two exterior attachment bars. The stirrups are attached to the sled by inserting the clamp end of the stirrups into the stirrup clamp and then tightening the clamp.

WARNING

Two people must lift the sled to or from the CT FTT or any flat table surface.

4.4 USE

The sled is ready to use upon completion of the installation. However, there are several additional actions needed before a patient is placed on the sled.

First the sled and accessories must be cleaned by the standard requirements of the user of any product that may come in contact with a patient. Second, the sled pad is normally covered by a sheet and perhaps a sterile pad cover to protect the patient. It is important that the guide pins are not covered by either the sheet or the sterile pad. As a user moves the sled and patient, the pins must be visible to help the user see the position of the guide pins and to make sure none of the sheet and pad slip underneath the sled.

WARNING

Do not allow the sled drape to hide the guide pins or to slide underneath the sled as it is important that the user know exactly where the sled is on the FTT. Failure to control the draping materials may cause the sled to not lift correctly, to catch the draping materials under the sled or to be moved beyond the limits of the guide pins.

Lower the CT FTT as close to the floor as it allows. The patient then sits on the sled with their perineum as close to the foot end of the sled as possible. The stirrups are then adjusted with the patient's legs in place to make sure the patient is correctly supported. The CT table is raised to a normal height.

WARNING

Do not turn on the blower and inflate the air pillows without the guide pins in the vertical position.

The user then turns on the air blower and inflates the air pillows. This lifts the sled and allows the user to position the sled and patient as desired on the CT table. The air is turned off and the clinical team can then place appropriate brachytherapy inserts into the patient.

When the patient is ready for a CT scan, the air blower is turned on and the sled and patient moved along the CT FTT toward head end of the CT FTT. The air is then turned off and the patient is moved into the scanner by moving the CT table.

The patient is removed from the CT FTT by reversing the process. The patient should not be moved on the sled with the air pillows inflated at the same time that the CT table is moving.

WARNING

It is extremely easy to move a patient that has been lifted by the air pillow. However, two people should assist in moving the patient whenever the sled is supported by the air pillow. Alignment guide pins help insure that the sled remains on the CT FTT but when only one person moves the patient, that person may cause movements of the sled that defeat the purpose of the guide pins.

WARNING

There are no stops at either end of the CT FTT. It is important that the user control the sled as it is moved to the extreme ends of the CT FTT and prevent it from extending over the CT FTT.

4.4.1 Pinch Points

Whenever the sled is elevated by the air pillows, it is possible for the user or the patient to allow their fingers to go underneath the sled. When the blower is turned off, the sled could drop and pinch fingers beneath it.

WARNING

Prevent pinched fingers. Before turning off the air blower, confirm that there are no fingers underneath the sled. Patients and users should never allow their fingers to rest beneath the sled.

SECTION 5

SERVICING

5.1 GENERAL

The Diacor Zephyr Patient Transport Sled requires careful handling and cleaning following each use but generally requires minimal service.

5.2 CLEANING

The Zephyr Patient Transport Sled and the stirrup accessories experience noncritical patient contact. It is important to thoroughly clean these parts following each use.

5.2.1 Cleaning Method

After each use, wipe the surfaces of the board and the support accessories with wipes containing a mild cleaning and disinfecting solution of 14% alcohol and active quaternary ammonium chlorides or a similar disinfecting solution. (One such solution is offered by Professional Disposables International with a trade name of SANI-CLOTH® PLUS). After the cleaning process is complete, let the cleaned surfaces air dry. Do not use water as either a cleaning or rinsing agent. Never use aerosol cleaning sprays, cleaning agents, solvents or abrasive detergents.

5.3 PERIODIC MAINTENANCE

Periodic checks of the Zephyr Patient Transport Sled should be done to insure the parts are not worn and require repair or replacement.

5.3.1 Patient Support Pads

The foam patient support pads and cover may tear with use and should be replaced as needed. Replacements are available from Diacor.

5.3.2 Air Blower Filter

The filter in the air blower should be periodically cleaned or replaced. There are three screws that must be removed to separate the blower from the canister and allow access to the filter. The filter can be cleaned with water or replaced and the three screws returned to their original position. One of these screws is visible in Figure 2.3 near the top of the canister. Filter replacements are available from Diacor.

5.4 HANDLING AND STORAGE

Handle the sled and stirrups carefully to prevent damage. Store in a safe place when not used.

SECTION 6

WARRANTY

6.1 GENERAL

The Zephyr Patient Transport Sled and all the associated parts for this system are warranted by Diacor for a period of one (1) year from the date of shipment.

The Diacor warranty coverage is limited to defective materials or workmanship. The warranty is void if the Zephyr Patient Transport Sled has been damaged by accident, unreasonable or improper use, neglect, or other causes not arising out of defects in material or workmanship.

6.2 WARRANTY DISCLAIMERS

The express warranty provided herein is in lieu of any and all implied warranties arising out of the sale of the Zephyr Patient Transport Sled, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Diacor shall not be liable for loss of use of the Zephyr Patient Transport Sled or other incidental or consequential costs, expenses, or damages incurred by the customer or other user.

6.3 WARRANTY PERFORMANCE

During the stated warranty period, the Zephyr Patient Transport Sled will be repaired or replaced, at the option of Diacor, Inc., with a new or reconditioned Zephyr Patient Transport Sled when the units are returned shipping prepaid to Diacor, Inc., 2550 Decker Lake Blvd., Suite 26, West Valley City, Utah 84119. Please contact Diacor, 800-342-2679 or 801-467-0050, for a Return Material Authorization (RMA) prior to sending the defective unit to us. The replacement of a Zephyr Patient Transport Sled will not extend the expressed warranty stated herein beyond the original warranty period.

SECTION 7

TECHNICAL INFORMATION

7.1 GENERAL

7.2 SPECIFICATIONS

Weight	75 lb. 34 kg.
Length	60 in. 152.4 cm.
Height (with pads)	4.75 in. 12.07 cm.
Width	23 in. 58.4 cm.
Maximum Patient Weight	350 lb.. 159 kg.