

Owner's Manual

Thermal Sack Pressure Infuser

“a thermal maintenance device”

By *Smithworks*

FDA 510K # K060851 CE

Instructions and warranty information.

This manual should accompany the unit
and be held as a reference tool by the end user.

Read all information carefully **before** placing this equipment into service

Visit our website:

www.smithworksmedical.com

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Care Provider Information for the Thermal Sack Pressure Infuser

As referred to in this manual as “TSPI”

The following information will serve as a guide to most of the questions concerning the use and maintenance of the TSPI, by Smithworks.

- 1) The TSPI is designed to be a thermal maintenance device used with an iv fluid warmer, or cooler, as an adjunct device or accessory. The TSPI is not a “stand alone” iv fluid warmer or cooler.
- 2) The TSPI is designed for use in rescue operations where ambient temperatures will alter the “target temperature” of the iv fluids, operations that require rapid infusions of warmed, or cooled fluids, and operations where holding the iv bag above the patient may be difficult.
- 3) The TSPI is equipped with a “double zipper” enabling the care provider to “switch out” spent iv fluid bags with full bags without unzipping the entire unit.
- 4) There is a clear panel on the face of the TSPI. This enables the care provider to view the iv bag and monitor the drip chamber, and tubing.
- 5) The TSPI has an inner pouch designed to hold hot packs, or cold packs. For hot packs, we recommend the use of “Jack Frost insulated hot pack.” Do not use any other hot packs. The Jack Frost insulated hot pack delivers 110°F (43°C) for approximately 45 minutes. Other hot packs may reach temperatures up to 135°F and are not suitable replacements. Use of other hot packs will void our product liability insurance coverage.
- 6) Any cold packs used with the TSPI should not cool the iv fluid below the target temperature.
- 7) We strongly recommend continuous monitoring of the fluid temperature. This is best accomplished with our “Temperature Disk”. The Temperature Disk displays 3 target temperature ranges.
 - 1st range is for induced hypothermia protocol.
 - 2nd range is for drug storage temperatures.
 - 3rd range is for warmed iv fluid protocol.

The part number for this accessory is: “3ZTD011SMI”

Maintenance

The TSPI is a durable product designed for years of service. Should it become soiled, hand wash with mild detergent, rinse, and hang dry.

Warranty

3 year limited warranty

- 1.) If the assembly of the TSPI should fail due to materials, or workmanship deficiencies, Smithworks Medical, Inc. will repair, or replace the unit within the time limitations as seen below.
- 2.) Exposure to chemicals or UV that cause damage to the TSPI will void the warranty, and disqualify the product from our liability insurance.
- 3.) Improper cleaning or drying of the TSPI will void the warranty, and disqualify the product from our liability insurance.
- 4.) Physical abuse will void the warranty, and disqualify the product from our liability insurance.
- 5.) Any alterations, or unauthorized service will void the warranty, and disqualify the product from our liability insurance.
- 6.) Accidental damages will void the warranty, and disqualify the product from our liability insurance.
- 7.) Failure to use proper hot packs or cold packs (Jack Frost) will void the warranty, and disqualify the product from our liability insurance.
- 8.) Failure to use accessory "3ZTD011SMI" for temperature monitor purposes will disqualify the product from our liability insurance.

What is our policy on warranty? In all cases, follow the above parameters for use or service.

1st year we will cover parts, labor, & freight. Outside Contiguous USA (lower 48), freight charges to be paid by the customer.

2nd year we will cover labor, & freight. Outside Contiguous USA (lower 48), parts, & freight charges to be paid by the customer.

3rd year we will cover ½ the labor cost. Parts, freight & ½ labor to be paid by the customer.

This warranty is designed to protect the buyer and the manufacturer. We are confident no problems will arise; however, we extend a three (3) year limited warranty "the unit will function as represented." Should a failure occur, we will repair the unit. This warranty covers the repair or the replacement of the unit and is limited to such.