

JAN 10 1997

510(k) Summary : K 962983

a(1) Submitted by: Adroit Medical Systems, Inc.
1146 Carding Machine Rd.
Loudon, TN 37774
423-458-8600

Contact Person: Richard L. Studer
606-578-9927

Prepared on: July 27, 1996

a(2) Proprietary Name: **Sterile Soft-Temp**
Common Name: Hot/Cold Therapy Pads
Classification Name: Water Circulating Hot or Cold Pack

a(3) Adroit Medical Systems, Inc. believes that the **Sterile Soft-Temp** hot/cold therapy pads are substantially equivalent to the **Soft-Temp** hot/cold therapy pads presently distributed by Adroit as non-sterile products. These non-sterile products were the subject of a 510(k) which was approved in 1992.

a(4) **Sterile Soft-Temp** hot/cold therapy pads are flat flexible pads with interconnecting passages for the circulation of hot or cold water. They are available in various sizes and shapes. The main portion of the pads consists of two inner layers of polyurethane film sandwiched between two outer layers of nonwoven cloth. These materials are held together by a pattern of welds created in a heat press. This pattern of welds produces the interconnecting passages that allow the hot or cold water to circulate from the input to the output.

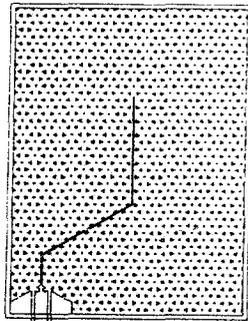
Two small diameter thermoplastic tubes are attached to the input and output areas of the pads, and fitted with plastic clamps for flow control and connectors. These connectors are used to attach the pads to longer tubes and adapters allowing connection to a source of hot or cold water. Thus a soft hot or cold flexible surface is available for thermal therapy.

Refer to the specification data sheet included with this 510(k) summary for material, dimensional and performance specifications.

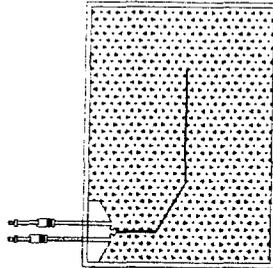
- a(5) **Sterile Soft-Temp** hot/cold therapy pads are intended for use in those situations where a physician determines that hot or cold therapy is necessary.
- a(6) The technological characteristics of **Sterile Soft-Temp** hot/cold therapy pads are identical to the technological characteristics of **Soft-Temp** hot/cold therapy pads presently distributed by Adroit. The only difference in the two product lines is that the **Sterile Soft-Temp** hot/cold therapy pads are sterilized and **Soft-Temp** hot/cold therapy pads are not.
- b(1) To determine that the gamma radiation process does not affect the performance of the finished devices, burst strength, leak, and flow tests were conducted on pads that were subjected to the gamma sterilization process and on pads that were not subjected to the gamma sterilization process. These tests showed that there was no substantial performance difference between sterile pads and non-sterile pads.
- b(2) No clinical tests were conducted.
- b(3) The fact that the design, construction, materials, and performance of **Sterile Soft-Temp** hot/cold therapy pads are the same as that of **Soft-Temp** hot/cold therapy pads leads to the conclusion that they are equally safe and effective.

Soft-Temp®

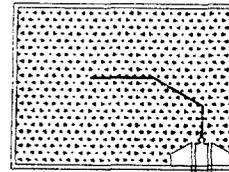
Sterile Heat / Cold-Therapy Pads



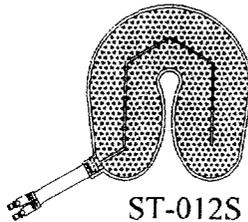
ST-024S
Large Pad, Sterile



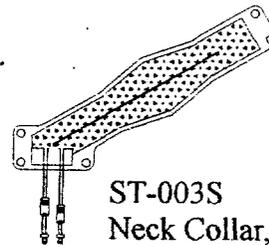
ST-020S
Medium Pad, Sterile



ST-017S
Small Pad, Sterile



ST-012S
Kneepad, Sterile



ST-003S
Neck Collar, Sterile

Materials of Construction

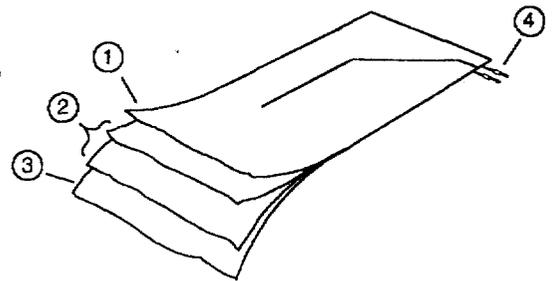
Soft-Temp blankets and pads are made from ① a top layer of 1.3 oz nonwoven cloth (25% polyester / 75% cellulose blend); ② two inner layers of 3.5 mil thick polyurethane film (95A durometer); ③ a bottom layer of 45 gram nonwoven cloth (70% rayon / 30% polypropylene blend); and ④ two 5/16" ID polyurethane tubes (63A durometer). Hose-sets, not shown, are made of vinyl.

Quality Assurance

All blankets and pads are 100% leak tested at 11psi-air.

Sterilization Method

Gamma Radiation.



Item No.	width	length	dry weight	flow rate	max/min temp. °F	patient weight
ST-024S	18"	24"	5 oz	23 gph	38/107°	300 lb
ST-020S	14"	20"	4 oz	23 gph	38/107°	300 lb
ST-017S	12"	17"	3 oz	23 gph	38/107°	300 lb
ST-012S	13"	12"	2 oz	23 gph	38/107°	300 lb
ST-003S	4.75"	19"	2 oz	23 gph	38/107°	300 lb

