

**APPENDIX 2
Label Specifications**

PRINTED MATERIAL SPECIFICATION

Spec. No. 903426 Rev. A

Issue Date 10-13-02

Supersedes None

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Product Description: MPS® ITM Adapter (SIII)

Code No. 5001020

A. Dimensions: 8 ½ W X 11 H

B. Description: 5001020, Carton Insert

1. Stock and color: White 20 lb. Bond.
2. Style: See following page
3. Printing: Black Ink
4. Manufacturer's Joint: None
5. Copy Requirements: See following page
6. Other: Refer to Quest Inspection Procedure 900-01.

(Artwork Reference)

CAT. NO. 5001020

DESCRIPTION

MPS® ITM Adapter (SIII).

INDICATION FOR USE

The adapter is indicated to be used to affix the Quest MPS ITM to either side of the SIII heart lung machine.

CONTRAINDICATION

This product is designed and warranted for use with the Quest Myocardial Protection System (MPS) only. Use with other systems is contraindicated. This product is not designed, sold, or intended for use except as indicated.

WARNINGS AND CAUTIONS

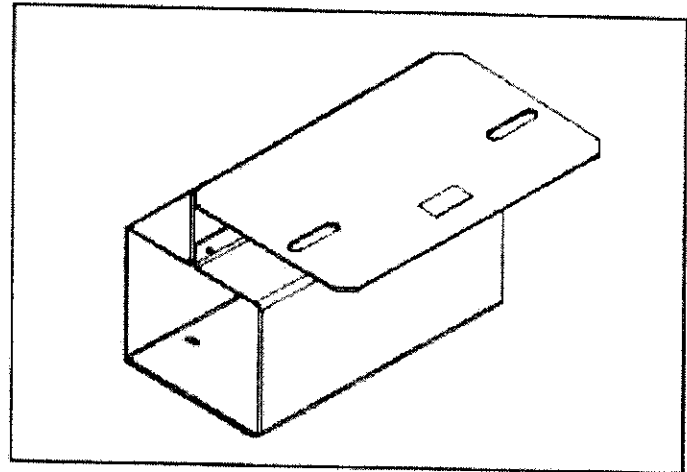
Read instructions carefully. The attending clinician is solely responsible for the setup and use of this device.

For use with Quest's MPS System only. All claims void if used separately.

INSTRUCTIONS FOR USE

For installation with MPS:

1. Remove MPS ITM Adapter and hardware from the package.
2. Prepare an open instrument location on the SIII console by removing the two positioning pins that stick up from the base plate.
3. Align the slots on the ITM adapter with the threaded holes in the base plate of the SIII console.
4. Install 5001013, MPS Console Adapter (SIII) per instructions contained within the 5001013 shipping container.
5. Install the ITM into the adapter and secure using four 10-32 phillips head screws (supplied).



For installation with SIII Pump Module:

1. Remove MPS ITM Adapter and hardware from the package.
2. Remove SIII Pump Module from SIII Console.
3. Align the slots up with the positioning pins in the base plate of the SIII console.
4. Replace SIII Pump Module.
5. Install the ITM into the adapter and secure using four 10-32 phillips head screws (supplied).

*The MPS® and MPS® Sterile Disposables are covered under one or more of the following U.S. patents.
5,385,540 | 5,638,737 | 5,573,502 | 5,645,531 | 5,588,816 | Patents Pending
Stöckert Instrumente GmbH