



Medical Compression Systems

Document Title- PRODUCT EXPERIENCE FORM

Document No. R-QAP-19-1-F-09-R04

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APPLICATION NO. H
(TO BE FILLED BY MCS)

DEVICE S.N -

DATE OF REPORT:
(MM/DD/YYYY)

DATE OF OCCURRENCE:
(MM/DD/YYYY)

(ALL FOLLOWING DATA TO BE FILLED BY COSTUMER)

CONTACT INFO:

HOSPITAL/CLINIC NAME:

STREET ADDRESS:

CITY: STATE: ZIP:

CONTACT PERSON'S INFO:

CONTACT PERSON AND POSITION:

E-MAIL ADDRESS:

PHONE NUMBER:

For Device Returns: PLEASE MARK THE DEVICE TYPE BEING RETURNED: (For other returns go to next section)

- ActiveCare[®]/ActiveCare OR[®]
- ActiveCare+S.F.T.[®]
- HomeCare ActiveCare+S.F.T.[®]

PRODUCT USAGE TYPE	<input type="checkbox"/> MEDICAL USE (AT HOSPITAL OR CLINIC)
	<input type="checkbox"/> HOME USE
	<input type="checkbox"/> OTHER (DESCRIBE HERE):

REASON FOR RETURNING PRODUCT:	<input type="checkbox"/> DEVICE FAILURE
	<input type="checkbox"/> END OF AGREEMENT
	<input type="checkbox"/> OTHER (DESCRIBE HERE):

IN CASE OF FAILURE, PLEASE DESCRIBE THE PROBLEM, BY CHECKING THE BOX BELOW:

- Was the failure discovered while a patient was using the device? Yes No
- Did the failure occur while the device was plugged into the wall unit (with AC/DC Adapter) or on Battery? AC/DC Adapter (Please return the adapter that was in use) Battery
- Please describe in detail the events leading up to the discovery of the failure: _____

- Was anyone adversely involved during the event? Yes- Patient Yes-Operator No Unknown
4a. Please describe the event in as much detail as possible (type of injury, how the clinical harm was resolved etc.)

Describe Device Failure: (Check all that apply)

- Sleeves Inflation: Sleeve Batch No. _____ Error Indicator _____ Power: AC/DC Adapter: Lot Code _____
- No Inflation (both sleeves)
 - Partial Inflation (some cells do no inflate)
 - Both sleeves inflate
 - Steady ON
 - Blinking
 - Steady OFF
 - Battery does not charge
 - Unit does not work on battery
 - Unit does not work on adapter
 - No power issue with the device

- Mechanical Issue: Broken case The device does not have a mechanical issue
- Other: Device Error Message: Other:

PLEASE RETURN ALL PARTS AND COMPONENTS, SUCH AS AC/DC ADAPTER AND EXTENSION TUBES WITH THE DEVICE, PLEASE MARK BELOW THE ACCESSORIES YOU ARE RETURNING AND MARK DEVICE S/N ON THE ACTUAL ACCESSORIES:

- AC/DC ADAPTER
- EXTENSION TUBES: LOT CODE
- NONE OF THE ABOVE



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REMARKS: _____

For Returning Other Products (not with devices):

PLEASE MARK THE PRODUCT(S) BEING RETURNED:

AC/DC Adapter: Lot Code _____ Sleeves: Batch No. _____ Extension tubes: Lot Code _____ Other

PLEASE SPECIFY THE PRODUCT TYPE (P.N OR DESCRIPTION) AND THE REASON FOR SENDING IT BACK:

TO ISSUE A RGA, PLEASE COMPLETE THIS FORM AND FAX TO 888-738-9992 OR EMAIL TO CustomerService@mcsmed.com