# MEDICAL DEVICE RECALL RESPONSE FORM

## ASP Global, Expressaire, and MPR Branded Sterile Disposable Tourniquet Cuff Products Recall – Customer Acknowledgement & Inventory Confirmation

**Date of Response:**

## Response Form

### 1. Customer Information

Customer Name:

Street Address:

City, State, Zip Code:

### 2. Recall Scope

This recall applies to certain **ASP Global, Expressaire, and MPR branded Sterile Disposable Tourniquet Cuff Products** manufactured between September 2016 and March 2023. A full list of impacted product models and descriptions is provided in **Appendix A: Affected Item Codes, Lot Numbers and UDI Information**.

### 3. Acknowledgement

Check all that apply:

- ☐ I have read and understood the recall instructions provided in the letter.
- ☐ I have checked my inventory and do not have any affected products.
- ☐ I have checked my inventory and have affected products-Complete Section 4.
- ☐ Adverse events associated with recalled products.

If you are aware of any adverse events that you have not previously reported to ASP Global or to FDA, please describe below and report to FDA MedWatch (see recall notification for details)

## 4. Affected Product Information Table

Please complete the table below with information regarding your inventory of affected products.

☐ Check this box if you do **not** have any affected products

| Item Code | Lot Number | Quantity in Inventory | Quantity Destroyed | Quantity Returned |
|---|---|---|---|---|
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## 5. Additional Comments

## 6. Customer Actions

Check all that apply:

- ☐ I have immediately discontinued use of any affected ASP Global, Expressaire, and MPR branded Sterile Disposable Tourniquet Cuff products.
- ☐ I have no inventory of the affected products, OR
- ☐ I have quarantined inventory documented in Section 4 and would like to dispose of it in the following way [select (a) or (b) below].
  - ☐ (a) I have disposed of unused products listed in table in Section 4 in accordance with my facility's standard procedures for non-hazardous medical device disposal.
  - ☐ (b) I am returning unused products listed in table in Section 4 to ASP Global for disposal and would like a Return Material Authorization (RMA).

## 7. Signature of Receipt

Name / Title:

Telephone Number:

Email Address:

Signature:

Date:

## 8. Submission Instructions

Please return the completed form(s) via email to: FieldActions@aspglobal.com

Or you may mail your completed forms to:

ASP Global, LLC

7800 Third Flag Parkway

Austell, GA 30168

*Attention: Field Actions – Tracy Weldon*

## Appendix A: Affected Item Codes, Lot Numbers and UDI Information

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| **Expressaire Branded Sterile Tourniquet Cuff Impacted Products Item Codes** | | | | |
| 1 | 553322 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 1-LINE (CS 18) WHITE | (01) 00885914010532 | S0922STY, R0310STY, R0801STY, Q0930STY, P0620STY, O0815STY, N0730STY, M0930STY |
| 2 | 553323 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 2-LINE (CS 18) WHITE | (01) 00885914010549 | Q1115STY |
| 3 | 564001 | DISPOSABLE TOURNIQUET CUFF, 8" X 2.5" 2-LINE (CS 10) | (01) 00885914044513 | Q0301STY |
| 4 | 564003 | DISPOSABLE TOURNIQUET CUFF, 12" X 3.5" 2-LINE (CS 10) PLUM | (01) 00885914044537 | S0922STY, S1101STY, Q0930STY, Q1115STY, P1015STY, M0730STY, M0930STY, M1230STY |
| 5 | 564005 | DISPOSABLE TOURNIQUET CUFF, 15" X 4" 2-LINE (CS 10) GRAY | (01) 00885914044551 | P0325STY |
| 6 | 564006 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 1-LINE (CS 10) RED | (01) 00885914044568 | S0922STY, S1101STY, S1214STY, R0310STY, R0601STY, R0801STY, R1101STY, R1201STY, Q0930STY, Q1115STY, P1015STY, O0120STY, N0330STY, N0730STY, M0130STY, M0430STY, M0730STY, M0930STY, M1230STY |
| 7 | 564007 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 2-LINE (CS 10) RED | (01) 00885914044575 | S0823STY, S0922STY, S1101STY, R0310STY, R0801STY, R1101STY, R1201STY, Q1115STY, P0325STY, P0620STY, N0730STY, M0130STY, M0730STY, M0930STY, M1230STY |
| 8 | 564008 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 1-LINE (CS 10) YELLOW | (01) 00885914044582 | S0823STY, S0922STY, S1101STY, S1214STY, R0310STY, R0601STY, R0801STY, R1101STY, Q0301STY, Q0930STY, Q1115STY, P0325STY, P0620STY, P1015STY, N0330STY, N0730STY, M0730STY, M0930STY |
| 9 | 564009 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 2-LINE (CS 10) YELLOW | (01) 00885914044599 | S0922STY, S1101STY, R0801STY, R1101STY, Q0301STY, Q1115STY, P0325STY, P0620STY, P1015STY, O0815STY, N0330STY, N0730STY, M0130STY, M0430STY, M0730STY, M0930STY, M1230STY |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| 10 | 564010 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 1-LINE (CS 10) WHITE | (01) 00885914044605 | S0823STY, S0922STY, S1101STY, R0601STY, R1101STY, Q0301STY, Q0930STY, Q1115STY, P0325STY, P0620STY, P1015STY, M0730STY |
| 11 | 564011 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 2-LINE (CS 10) WHITE | (01) 00885914044612 | S0823STY, S0922STY, S1101STY, R0310STY, R0601STY, R0801STY, R1101STY, R1201STY, Q0301STY, Q0930STY, Q1115STY, P0325STY, P0620STY, P1015STY, O0815STY, N0330STY, N0730STY, M0730STY, M0930STY, M1230STY |
| 12 | 564012 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 1-LINE (CS 10) BLUE | (01) 00885914044629 | S0922STY, S1101STY, R0601STY, R1101STY, Q0301STY, Q1115STY, P0325STY, P0620STY, P1015STY, O1020STY, N0730STY, M0130STY, M0430STY, M0730STY, M0930STY, M1230STY |
| 13 | 564013 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 2-LINE (CS 10) BLUE | (01) 00885914044636 | S0823STY, S0922STY, S1101STY, R0801STY, R1101STY, Q0301STY, Q0930STY, P0325STY, P0620STY, O0815STY, N0330STY, M0130STY, M0430STY, M0730STY, M0930STY, M1230STY |
| 14 | 564014 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 1-LINE (CS 10) GREEN | (01) 00885914044643 | S0823STY, S0922STY, S1101STY, S1214STY, R0601STY, R1101STY, Q0301STY, N0730STY, M0130STY, M0730STY, M0930STY |
| 15 | 564015 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 2-LINE (CS 10) GREEN | (01) 00885914044650 | S0823STY, S0922STY, S1101STY, R1101STY, Q0301STY, Q1115STY, P0620STY, O0815STY, O1020STY, N0730STY, M0130STY, M0730STY, M0930STY, M1230STY |
| 16 | 564017 | DISPOSABLE TOURNIQUET CUFF, 20" X 6" 1-LINE (CS 10) NAVY BLUE | (01) 00885914044674 | S0922STY, R0310STY, Q0301STY, Q1115STY, O0815STY, O1020STY, N0330STY |
| 17 | 564019 | DISPOSABLE TOURNIQUET CUFF, 26" X 6" 1-LINE (CS 10) ORANGE | (01) 00885914044698 | R0310STY |
| 18 | 564044 | DISPOSABLE TOURNIQUET CUFF, 38" X 4" 1-LINE (CS 10) | (01) 00885914044964 | Q0301STY |
| 19 | A70107000 | DISPOSABLE TOURNIQUET CUFF, 8" X 2.5" 1-LINE (CS 12) LIGHT BLUE | (01) 00885914035443 | R1101STY |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| 20 | A70107001 | DISPOSABLE TOURNIQUET CUFF, 8" X 2.5" 2-LINE (CS 12) LIGHT BLUE | (01) 00885914035450 | R1201STY, Q0301STY |
| 21 | A70107002 | DISPOSABLE TOURNIQUET CUFF, 12" X 3.5" 1-LINE (CS 12) PLUM | (01) 00885914035467 | S0922STY, S1101STY, R0601STY, R0801STY, Q0301STY, P1015STY, O0120STY, N0730STY, M0130STY |
| 22 | A70107003 | DISPOSABLE TOURNIQUET CUFF, 12" X 3.5" 2-LINE (CS 12) PLUM | (01) 00885914035474 | R0601STY, Q0301STY, Q1115STY, P0620STY, P1015STY, O0120STY, O0815STY, N0330STY, M0130STY, M0430STY, M0730STY, M0930STY |
| 23 | A70107004 | DISPOSABLE TOURNIQUET CUFF, 15" X 4" 1-LINE (CS 12) GRAY | (01) 00885914035481 | R0310STY, R1201STY |
| 24 | A70107005 | DISPOSABLE TOURNIQUET CUFF, 15" X 4" 2-LINE (CS 12) GRAY | (01) 00885914035498 | S0922STY, S1214STY, R0601STY, R0801STY, Q0301STY, Q1115STY, P0620STY, P1015STY, N0730STY, M0130STY, M0730STY, M0930STY |
| 25 | A70107006 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 1-LINE (CS 18) RED | (01) 00885914035504 | S0823STY, S0922STY, S1214STY, R0601STY, R1101STY, Q0930STY, Q1115STY, P0325STY, P1015STY, O0815STY, N0330STY, N0730STY, M0130STY, M0730STY, M0930STY |
| 26 | A70107007 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 2-LINE (CS 18) RED | (01) 00885914035511 | S0922STY, S1101STY, S1214STY, R1101STY, R1201STY, Q0301STY, Q1115STY, P0325STY, P1015STY, O0120STY, N0730STY, M1230STY, L0120STY |
| 27 | A70107008 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 1-LINE (CS 18) YELLOW | (01) 00885914035528 | S0823STY, S1101STY, R0310STY, R0601STY, R1101STY, R1201STY, Q1115STY, P0325STY, P1015STY, N0730STY, M1230STY, L0120STY |
| 28 | A70107009 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 2-LINE (CS 18) YELLOW | (01) 00885914035535 | S0823STY, R0310STY, R0601STY, R1101STY, R1201STY, Q0301STY, Q1115STY, P0325STY, O1020STY, N0730STY, L0120STY |
| 29 | A70107010 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 1-LINE (CS 18) BLUE | (01) 00885914035542 | S0823STY, S0922STY, S1101STY, R0310STY, R1101STY, Q0301STY, Q0930STY, P0325STY, P1015STY, O0120STY, O0815STY, N0730STY, M1230STY, L0120STY |
| 30 | A70107011 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 2-LINE (CS 18) BLUE | (01) 00885914035559 | S0823STY, S0922STY, S1101STY, S1214STY, R0601STY, R0801STY, Q0301STY, N0730STY, M0130STY, M0930STY, M1230STY, L0120STY |
| 31 | A70107012 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 1-LINE (CS 12) GREEN | (01) 00885914035566 | S0922STY, S1101STY, R0601STY, R1101STY, Q0930STY, Q1115STY, P1215STY, O1020STY, N0730STY, M0730STY, M0930STY |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| 32 | A70107013 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 2-LINE (CS 12) GREEN | (01) 00885914035573 | S0922STY, R0310STY, R0601STY, R0801STY, Q1115STY, P0620STY, O0120STY, N0330STY, N0730STY, M0130STY, M0730STY, M0930STY, L0120STY |
| 33 | A70107014 | DISPOSABLE BB TOURNQUET CUFF, 20" X 6" DUAL BLADDER 1-LINE (CS 12) NAVY BLUE | (01) 00885914035580 | Q0930STY, Q1115STY |
| 34 | A70107016 | DISPOSABLE BB TOURNQUET CUFF, 26" X 6" DUAL BLADDER, 1-LINE (CS 12) ORANGE | (01) 00885914035603 | P0325STY |
| 35 | A70107017 | DISPOSABLE BB TOURNQUET CUFF, 26" X 6" DUAL BLADDER, 2-LINE (CS 12) ORANGE | (01) 00885914035610 | Q0301STY |
| **ASP Global Branded Sterile Tourniquet Cuff Products Impacted Item Codes** | | | | |
| 36 | ASP-564003 | DISPOSABLE TOURNIQUET CUFF, 12" X 3.5" 2-Line, Plum | (01) 00840216106703 | P1015STY, P1215STY, N0330STY, N0530STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 37 | ASP-564006 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 1-Line, Red | (01) 00840216106710 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, N0730STY, M0130STY, M0730STY, M1015STY, M1101STY, M1115STY, L0310STY, L0325STY |
| 38 | ASP-564007 | DISPOSABLE TOURNIQUET CUFF, 18" X 4" 2-Line, Red | (01) 00840216106727 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, N0730STY, M0130STY, M0430STY, M0730STY, M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 39 | ASP-564008 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 1-Line, Yellow | (01) 00840216106734 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, M0130STY, M0430STY, M0730STY, M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 40 | ASP-564009 | DISPOSABLE TOURNIQUET CUFF, 24" X 4" 2-Line, Yellow | (01) 00840216106741 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, M0130STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 41 | ASP-564010 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 1-Line, White | (01) 00840216106758 | P1015STY, P1215STY, O1020STY, N0330STY, N0530STY, M0130STY, M0430STY, M0730STY, M0930STY, |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| | | | | M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 42 | ASP-564011 | DISPOSABLE TOURNIQUET CUFF, 30" X 4" 2-Line, White | (01) 00840216106765 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, M0430STY, M0730STY, M1015STY, M1101STY, M1115STY, L0228STY, L0310STY, L0325STY |
| 43 | ASP-564012 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 1-Line, Blue | (01) 00840216106772 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, N0730STY, M0130STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0310STY, L0325STY |
| 44 | ASP-564013 | DISPOSABLE TOURNIQUET CUFF, 34" X 4" 2-Line, Blue | (01) 00840216106789 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, M0130STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0310STY, L0325STY |
| 45 | ASP-564014 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 1-Line, Green | (01) 00840216106796 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, M0130STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0310STY, L0325STY |
| 46 | ASP-564015 | DISPOSABLE TOURNIQUET CUFF, 44" X 4" 2-Line, Green | (01) 00840216106802 | P1015STY, P1215STY, O0815STY, O1020STY, N0330STY, N0530STY, N0730STY, M0130STY, M0430STY, M0730STY, M0930STY, M1015STY, M1101STY, M1115STY, L0310STY, L0325STY |
| **MPR Branded Sterile Tourniquet Cuff Products Impacted Item Codes** | | | | |
| 47 | DB-7018-01Q | DISPOSABLE TOURNIQUET CUFF 20" DUAL BLADDER, 1 LINE (10) | UDI was not applicable at time of manufacture. | N0330STY, Q1115STY |
| 48 | DB-7020-02Q | DISPOSABLE TOURNIQUET CUFF 20" DUAL BLADDER, 2 LINE (10) | UDI was not applicable at time of manufacture. | Q1115STY |
| 49 | DB-7024-02Q | SINGLE USE TOURNIQUET CUFF 26" DUAL BLADDER, 2 LINE (10) | UDI was not applicable at time of manufacture. | N0330STY |
| 50 | DT-7018-01Q | SINGLE USE TOURNIQUET CUFF 18" 1 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, Q0301STY, P1015STY, N0330STY, N0530STY |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| 51 | DT-7024-01Q | SINGLE USE TOURNIQUET CUFF 24" 1 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, R1201STY, Q0301STY, Q1115STY, P1015STY, N0330STY |
| 52 | DT-7024-02Q | SINGLE USE TOURNIQUET CUFF 24" 2 LINE (10) | UDI was not applicable at time of manufacture. | R1201STY, Q0301STY, Q1115STY, O1020STY, N0330STY, N0530STY, M0930STY |
| 53 | DT-7030-01Q | SINGLE USE TOURNIQUET CUFF 30" 1 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, P1015STY, N0330STY, N0730STY |
| 54 | DT-7030-02Q | SINGLE USE TOURNIQUET CUFF 30" 2 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, R1201STY, Q1115STY, O1020STY, N0330STY, N0530STY, N0730STY |
| 55 | DT-7034-01Q | SINGLE USE TOURNIQUET CUFF 34" 1 LINE (10) | UDI was not applicable at time of manufacture. | R1201STY, Q1115STY, P1015STY |
| 56 | DT-7034-02Q | SINGLE USE TOURNIQUET CUFF 34" 2 LINE (10) | (01) 00840001403239 | S0823STY, S1101STY, R1201STY, Q1115STY, O1020STY, N0330STY, N0530STY, M0930STY |
| 57 | DT-7044-01Q | SINGLE USE TOURNIQUET CUFF 44" 1 LINE (10) | UDI was not applicable at time of manufacture. | R1201STY, P1015STY |
| 58 | DT-7044-02Q | SINGLE USE TOURNIQUET CUFF 44" 2 LINE (10) | (01) 00840001403253 | S0823STY, R1201STY, N0330STY, N0530STY, M0730STY, M0930STY |
| 59 | DT-7108-02Q | SINGLE USE TOURNIQUET CUFF 8" 2 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, R1201STY |
| 60 | DT-7112-01Q | SINGLE USE TOURNIQUET CUFF 12" 1 LINE (10) | UDI was not applicable at time of manufacture. | O1020STY, N0530STY |
| 61 | DT-7112-02Q | SINGLE USE TOURNIQUET CUFF 12" 2 LINE (10) | UDI was not applicable at time of manufacture. | Q0301STY |
| 62 | DT-7115-01Q | SINGLE USE TOURNIQUET CUFF 15" 1 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY |

| Line Item | Item Codes | Description | UDI | Lot Numbers |
|---|---|---|---|---|
| 63 | DT-7115-02Q | SINGLE USE TOURNIQUET CUFF 15" 2 LINE (10) | UDI was not applicable at time of manufacture. | S1101STY, P1015STY, N0330STY |
| 64 | DT-7218-02Q | DISPOSABLE TOURNIQUET CUFF 18" 2 LINE (10) | (01) 00840001403314 | S0922STY, S1101STY, R1201STY, Q1115STY, P1015STY, N0530STY |