



Headquarters
Wright Medical Technology, Inc.

1023 Cherry Road
Memphis, TN 38117

901 867 9971
wmt.com

URGENT: MEDICAL DEVICE VOLUNTARY RECALL

July 25, 2014

[Recipient Name]
[Company Name]
[Street Address]
[City, ST ZIP Code]

Dear [Recipient Name]:

This letter is to inform you of a voluntary product recall of specific lots of Wright Medical's CLAW[®] and CLAW[®] II plates intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

As an outcome of an investigation from a field complaint, Wright Medical discovered that certain CLAW[®] and CLAW[®] II plates were manufactured from an incorrect raw material. The raw material specified for CLAW[®] and CLAW[®] II plates is stainless steel meeting the requirements of ASTM F139 in a cold worked condition, however the material used meets the requirements of ASTM F139 stainless steel, but is in an annealed condition, which has reduced strength and increased ductility. This difference could result in a plate's failing intraoperatively, which would likely cause a delay of approximately 15 minutes while the affected plate is removed and a replacement plate is located. If the material difference is not detected intraoperatively, there is a remote possibility of a loss of fixation between the implant and bone prior to fusion, which could result in the need for revision surgery.

Although this issue was noted in a field complaint, to date, Wright Medical has not been made aware of any reports of patient injury or revision surgery.

Please see below a picture of the 2-hole CLAW[®] plate for your information:



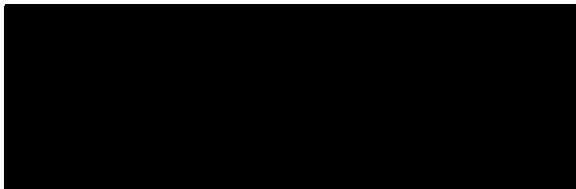
The Food and Drug Administration has knowledge of this voluntary recall. Our records indicate that you or your customers could have received some CLAW[®] and CLAW[®] II plates manufactured from the incorrect raw material. A list of the affected part and lot numbers is attached to this letter.

Please examine your inventory for these products and check it against the attached list. Please immediately quarantine all recalled products you have found, and return all affected product to Wright Medical as soon as possible. Contact Customer Service at 800-238-7117 for return instructions and replacement inventory.

Also, please immediately complete the attached response form, confirming your receipt of this notice and the status of product(s) on hand, and return a copy to us by facsimile to 901-867-7401.

Finally, we sincerely apologize for this inconvenience and want to assure you that Wright Medical is committed to providing you with the highest quality technology for your patients. Please do not hesitate to contact [REDACTED] with any concerns or questions.

Sincerely,



Senior Director of Global Quality
Tissue Bank Director



| Lot Number | Catalog Number | Description |
|------------|----------------|-------------------------------|
| 1509955 | 40130130 | CLAW® 3.5MM PLATE 2 HOLE 30MM |
| 1487673 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1487674 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1487675 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1487676 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1490003 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1512150 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1512151 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1519497 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1519498 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1522019 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1522020 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1523747 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1523748 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1537072 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1537073 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1537162 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1539399 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1541615 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1541616 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1543148 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1543149 | 40240215 | CLAW® II 2 HOLE 15MM |
| 1490004 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490005 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490199 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490200 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490201 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490202 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1518483 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1519493 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1519494 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1519495 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1522021 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1522898 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1522899 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1522900 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1523735 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1523736 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1526519 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1526520 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1526521 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1538760 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1538761 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1539402 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1540715 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1540716 | 40240220 | CLAW® II 2 HOLE 20MM |

| Lot Number | Catalog Number | Description |
|------------|----------------|-----------------------------|
| 1540717 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1542703 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1542704 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1542776 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1543491 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1543891 | 40240220 | CLAW® II 2 HOLE 20MM |
| 1490367 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1490368 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1512152 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1521232 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1523734 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1523746 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1537160 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1537161 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1539401 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1541613 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1541614 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1542652 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1542774 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1542775 | 40240225 | CLAW® II 2 HOLE 25MM |
| 1487670 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1487671 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1487672 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1512149 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1519496 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1523745 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1534796 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1537159 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1539400 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1540714 | 40240230 | CLAW® II 2 HOLE 30MM |
| 1512153 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1518480 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1532497 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1538075 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1538076 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1538332 | 40242020 | CLAW® II STRAIGHT 20 X 20MM |
| 1513144 | 40242025 | CLAW® II STRAIGHT 20 X 25MM |
| 1518479 | 40242025 | CLAW® II STRAIGHT 20 X 25MM |
| 1534798 | 40242025 | CLAW® II STRAIGHT 20 X 25MM |
| 1538331 | 40242025 | CLAW® II STRAIGHT 20 X 25MM |
| 1543489 | 40242025 | CLAW® II STRAIGHT 20 X 25MM |
| 1517327 | 40242525 | CLAW® II STRAIGHT 25 X 25MM |
| 1538333 | 40242525 | CLAW® II STRAIGHT 25 X 25MM |
| 1543490 | 40242525 | CLAW® II STRAIGHT 25 X 25MM |
| 1543488 | 40S20020 | CLAW® PLATE 20MM INTERAXIS |

CLAW[®] and CLAW[®] II plate VOLUNTARY RECALL

Please sign and return this form

Facsimile #: 901-867-7401

Email: complaints@wmt.com

Status of product:

- No product on hand
- Product previously in inventory but none on hand at this time
- Never received product
- Product found in inventory _____
- Amount being returned _____

Signed: _____

Printed Name: _____

Distributor/Hospital Name: _____

Date: _____

Preferred Contact Information: _____