# Information from the MAUDE Database

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|---|---|
| **Device** | mesh, surgical, polymeric |
| **Regulation Description** | Surgical mesh. |
| **Product Code** | FTL |
| **Regulation Number** | 878.3300 |
| **Device Class** | 2 |

**Manufacturer** ETHICON

| **Medical Device Reporting - MDR Summary** | |
|---|---|
| **2007** | |
| Death | 1 |
| Injury | 332 |
| Malfunction | 63 |
| Other | 1 |
| **2008** | |
| Death | 4 |
| Injury | 416 |
| Malfunction | 58 |
| Other | 2 |
| **2009** | |
| Death | 1 |
| Injury | 414 |
| Invalid Data | 2 |
| Malfunction | 23 |
| Other | 1 |
| **2010** | |
| Death | 4 |
| Injury | 491 |
| Invalid Data | 1 |
| Malfunction | 32 |
| **2011** | |
| Death | 1 |

| | | |
|---|---|---|
| | Injury | 192 |
| | Malfunction | 14 |
| | Other | 1 |

| **MDR Distribution by Brand** | |
|---|---|
| TENSION FREE VAGINAL TAPE | 740 |
| PROCEED MULTI-LAYER LAMINATE MESH | 283 |
| PROLIFT PELVIC FLOOR REPAIR | 264 |
| ULTRAPRO MESH | 78 |
| PROLIFT +M PELVIC FLOOR REPAIR | 76 |
| PROCEED VENTRAL PATCH | 74 |
| PROLENE POLYPROPYLENE MESH | 66 |
| GYNECARE GYNEMESH PS | 61 |
| PROLENE HERNIA SYSTEM | 47 |
| PROSIMA PELVIC FLOOR REPAIR KIT | 46 |
| UNKNOWN MESH PRODUCT (EWHU) | 42 |
| PHYSIOMESH | 34 |
| ULTRAPRO HERNIA SYSTEM | 31 |
| UNKNOWN MESH PRODUCT | 13 |
| UNK MESH PRODUCT (EWHU) | 12 |
| VYPRO MESH | 10 |
| PROCEED* MULTI-LAYER LAMINATE MESH | 9 |
| GYNECARE TVT | 7 |
| PROLENE MESH | 6 |
| PROLIFT | 6 |
| VICRYL (POLYGLACTIN 910) MESH | 5 |
| PROCEED | 5 |
| GYNECARE PROLIFT | 5 |
| GYNEMESH | 4 |
| MERSILENE POLYESTER FIBER MESH | 4 |
| UNK MESH PRODUCT | 4 |
| ULTRAPRO HERNIA PLUG | 4 |

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|---|---|
| GYNECARE MORCELLEX TISSUE MORCELLATOR | 3 |
| GYNECARE | 3 |
| ETHICON PROLENE MESH | 2 |
| ETHICON | 2 |
| GYNECARE TVT SYSTEM | 2 |
| MESH | 2 |
| PROCEED MULTI LAYER LAMINATE MESH | 2 |
| PROCEED MUTLI-LAYER LAMINATE MESH | 2 |
| TVT-O | 2 |
| TVT | 2 |
| TENSION FREE VAGINAL TYPE | 2 |
| TENSION FREE VAGIONAL TAPE | 2 |
| TENSION FREE VAGNIAL TAPE | 2 |
| TENSION FREE VIGINAL TAPE | 2 |
| TENSION FREE VAGINAL TAPE | 2 |
| UNK | 2 |
| UNKNOWN PRODUCT | 2 |
| UNKNOWN PROLENE MESH | 1 |
| UNKNOWN SUTURE PRODUCT | 1 |
| UNKNWON MESH PRODUCT | 1 |
| UNK MESH PRODUCT (EHWU) | 1 |
| ULTRAPRO PLUG | 1 |
| UNKNOWN ETHICON PRODUCT | 1 |
| UNKNOWN MESH | 1 |
| UNKNOWN MESH PRODUCT (EP) | 1 |
| TENSION FREE VAGINA TAPE | 1 |
| TENSION FREE VAGINAL TAP | 1 |
| TENSION FREE VAGINAL TAPE (TVT) SYSTEM | 1 |
| PROLIFT +M PELVIC FLOOR REPAIR | 1 |
| SECURE | 1 |
| PROLIFT ANTERIOR REPAIR | 1 |

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|---|---|
| PROLIFT KIT | 1 |
| PROLIFT MESH | 1 |
| PROLIFT PELVIC FLOOR REPAIR SYSTEM | 1 |
| PROLIFT PELVIC FLOOR RREPAIR | 1 |
| PROLIFT PELVIX FLOOR REPAIR | 1 |
| PROLIFT POSTERIOR MESH | 1 |
| PROLIFT TOTAL PELVIC REPAIR SYST | 1 |
| TENSION-FREE VAGINAL TAPE | 1 |
| TENSOIN FREE VAGINAL TAPE | 1 |
| THERMACHOICE | 1 |
| TENSION FREE VIAGINAL TAPE | 1 |
| TVT DEVICE | 1 |
| TVT GYNECARE | 1 |
| TVT MESH | 1 |
| TVT SECUR | 1 |
| TVT SECUR SYSTEM | 1 |
| PROCEED SURGICAL MESH | 1 |
| PROCEED VENTRA PATCH | 1 |
| PROCEED VENTRAL MESH PATCH | 1 |
| PROCEED MULTI-LAER LAMINATE MESH | 1 |
| PROCEED MULTI-LAYER LAMINATED MESH | 1 |
| PROCEED MULTILAYER LAMINATE MESH | 1 |
| MID URETHRAL SLING MESH | 1 |
| POLYPROPYLENE (MESH) | 1 |
| PROCEED 6X6 MESH | 1 |
| PROCEED HERNIA MESH | 1 |
| PROCEED MESH | 1 |
| PROCEED MULTI - LAYER LAMINATE MESH | 1 |
| PROLENE MESH SYSTEM | 1 |
| PROLENE OR % -AS LISTED WITH THE FDA- | 1 |
| PROCEED VENTRAL PATCH 6.4 X 6.4 CM | 1 |

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|---|---|
| PROLENE SOFT MESH | 1 |
| PROLENE SOFT POLYPROPYLENE MESH | 1 |
| PROLENE, MESH HERNIA REPAIR PATCH | 1 |
| PROLIF +M PELVIC FLOOR REPAIR | 1 |
| PROLIFE +M PELVIC FLOOR REPAIR | 1 |
| PROCEED, MULTI-LAYER LAMINATE MESH | 1 |
| PROLENE ETHICON MESH | 1 |
| PROLENE HERNIA MESH | 1 |
| PROLENE HERNIA SYSTEM - PHS MESH | 1 |
| PROLENE HERNIA SYSTEM MESH | 1 |
| PROLENE HERNIA SYSTEM MESH LEVEL A | 1 |
| GYNECARE TVT TAPE | 1 |
| GYNECARE TVT-O | 1 |
| GYNECURE PROLIFT TOTAL PELVIC FLOOR REPAIR SYSTEM | 1 |
| MERSILENE POLYSTER FIBER MESH | 1 |
| KUGEL HERNIA PATCH | 1 |
| KUGEL-BARD | 1 |
| GYNECARE PROLIFT - TOTAL PELVIC FLOOR REPAIR | 1 |
| GYNECARE PROLIFT TOTAL KITS FOR PROLAPSE UTERUS | 1 |
| GYNECARE PROSIMA PELVIC FLOOR REPAIR SYSTEM | 1 |
| GYNECARE TENSION-FREE VAGINAL TAPE-OBTURATOR SYSTEM | 1 |
| GYNECARE TOTAL VAGINAL MESH | 1 |
| GYNECARE TVT DEVICE PROLENE MESH | 1 |
| GYNECARE TVT OBTURATOR | 1 |
| GYNECARE TVT SECUR SYSTEM | 1 |
| GYNECARE TVT SECURE | 1 |
| GYNECARE TVT SLING | 1 |
| ETHICON ENDO-SURGERY, INC | 1 |
| ETHICON GYNECARE TVT TAPE | 1 |
| ETHICON INC. | 1 |
| ETHICON PHYSIOMESH | 1 |

| | |
|---|---|
| ETHICON PMII PROLENE MESH 3.6 SHEETS | 1 |
| ETHICON PMII PROLENE MESH 3X6 SHEETS | 1 |
| ETHICON PROCEED VENTRAL PATCH | 1 |
| ETHICON PROLENE MESH PATCH, 3X3 | 1 |
| ETHICON TVT-O | 1 |
| ANTERIOR PROLIFT | 1 |
| COATED VICRYL PLUS ANTIBACTERIAL (POLYGLACTIN 910) | 1 |
| GYNECARE ETHICON | 1 |
| GYNECARE GYNEMESH* PS | 1 |

| **Device Problems** | |
|---|---|
| Other (for use when an appropriate device code cannot be identified) | 1389 |
| Material erosion | 257 |
| Unknown (for use when the device problem is not known) | 123 |
| Tears, rips, holes in device, device material | 100 |
| Material perforation | 63 |
| Reaction | 15 |
| Implant extrusion | 4 |
| Break | 4 |
| Difficult to insert | 3 |
| Explanted | 2 |
| Migration of device or device component | 2 |
| Needle, dull | 1 |
| Material frayed | 1 |
| Failure to Adhere or Bond | 1 |
| Failure to deploy | 1 |
| Implant, removal of | 1 |
| Difficult to position | 1 |
| Bacterial contamination of device | 1 |
| Balloon leak(s) | 1 |
| Decrease in pressure | 1 |
| Device Issue | 1 |

| | |
|---|---|
| Device remains implanted | 1 |
| **Total Device Problems** | **1973** |

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftplc/tplc.cfm?id=FTL&min_report_year=2007&long_name=ETHICON

Go to the database and locate the search facility located top right and type in Ethicon tvt sling deaths, the information above will then show up.

The above information is only on one manufacturer there are many more, do a complete search to show the figures.

Don't forget this is only from people who decide to report adverse events imagine all those people who decide not to report their adverse event this is why the true figures are skewed!