

Profix Oxinium (cementless)/Profix Total Knee Investigation

Note: This analysis compares the Profix Oxinium (cless)/Profix femoral/tibial combination with all other total knee prostheses.

This combination has been identified as having a significantly higher rate of revision. For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the Prostheses with Higher than Anticipated Rates of Revision chapter of the most recent AOANJRR Annual Report, <https://aoanjrr.sahmri.com/annual-reports-2025>.

Note: Procedures using prostheses with no recorded use in 2024 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Profix Oxinium (cless)/Profix total knee combination is compared to all other total knee prostheses.

Table 1: Revision Rates of Primary Total Knee Replacement

| Component                     | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs<br>(95% CI) |
|-------------------------------|-----------|---------|------------|------------------------------------|
| Profix Oxinium (cless)/Profix | 33        | 75      | 779        | 4.24 (2.92, 5.95)                  |
| Other Total Knee              | 24707     | 721061  | 4535539    | 0.54 (0.54, 0.55)                  |
| TOTAL                         | 24740     | 721136  | 4536318    | 0.55 (0.54, 0.55)                  |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 2

## Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Profix Oxinium (cless)/Profix total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision (95% CI) of Primary Total Knee Replacement

| CPR                           | 1 Yr             | 2 Yrs             | 3 Yrs             | 4 Yrs             | 5 Yrs             | 6 Yrs             | 7 Yrs             | 8 Yrs             |
|-------------------------------|------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Profix Oxinium (cless)/Profix | 13.3 (7.4, 23.4) | 33.3 (23.9, 45.2) | 36.1 (26.4, 48.1) | 37.5 (27.6, 49.5) | 37.5 (27.6, 49.5) | 37.5 (27.6, 49.5) | 37.5 (27.6, 49.5) | 40.5 (30.3, 52.6) |
| Other Total Knee              | 1.0 (1.0, 1.0)   | 1.8 (1.8, 1.9)    | 2.4 (2.4, 2.4)    | 2.8 (2.8, 2.8)    | 3.2 (3.1, 3.2)    | 3.5 (3.4, 3.5)    | 3.8 (3.7, 3.8)    | 4.1 (4.0, 4.2)    |

| CPR                           | 9 Yrs             | 10 Yrs            | 11 Yrs            | 12 Yrs            | 13 Yrs            | 14 Yrs            | 15 Yrs            | 16 Yrs            |
|-------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| Profix Oxinium (cless)/Profix | 42.0 (31.7, 54.2) | 42.0 (31.7, 54.2) | 42.0 (31.7, 54.2) | 42.0 (31.7, 54.2) | 43.9 (33.3, 56.1) | 43.9 (33.3, 56.1) | 43.9 (33.3, 56.1) | 46.0 (35.1, 58.5) |
| Other Total Knee              | 4.4 (4.3, 4.5)    | 4.7 (4.7, 4.8)    | 5.1 (5.0, 5.1)    | 5.4 (5.3, 5.5)    | 5.7 (5.6, 5.8)    | 6.0 (5.9, 6.1)    | 6.4 (6.3, 6.5)    | 6.8 (6.7, 7.0)    |

| CPR                           | 17 Yrs            | 18 Yrs            | 19 Yrs            | 20 Yrs            | 21 Yrs            | 22 Yrs         | 23 Yrs         |
|-------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|----------------|----------------|
| Profix Oxinium (cless)/Profix | 46.0 (35.1, 58.5) | 46.0 (35.1, 58.5) | 46.0 (35.1, 58.5) | 46.0 (35.1, 58.5) | 46.0 (35.1, 58.5) |                |                |
| Other Total Knee              | 7.3 (7.1, 7.4)    | 7.6 (7.4, 7.8)    | 7.9 (7.7, 8.1)    | 8.1 (7.9, 8.3)    | 8.4 (8.1, 8.6)    | 8.5 (8.2, 8.8) | 8.6 (8.3, 8.9) |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

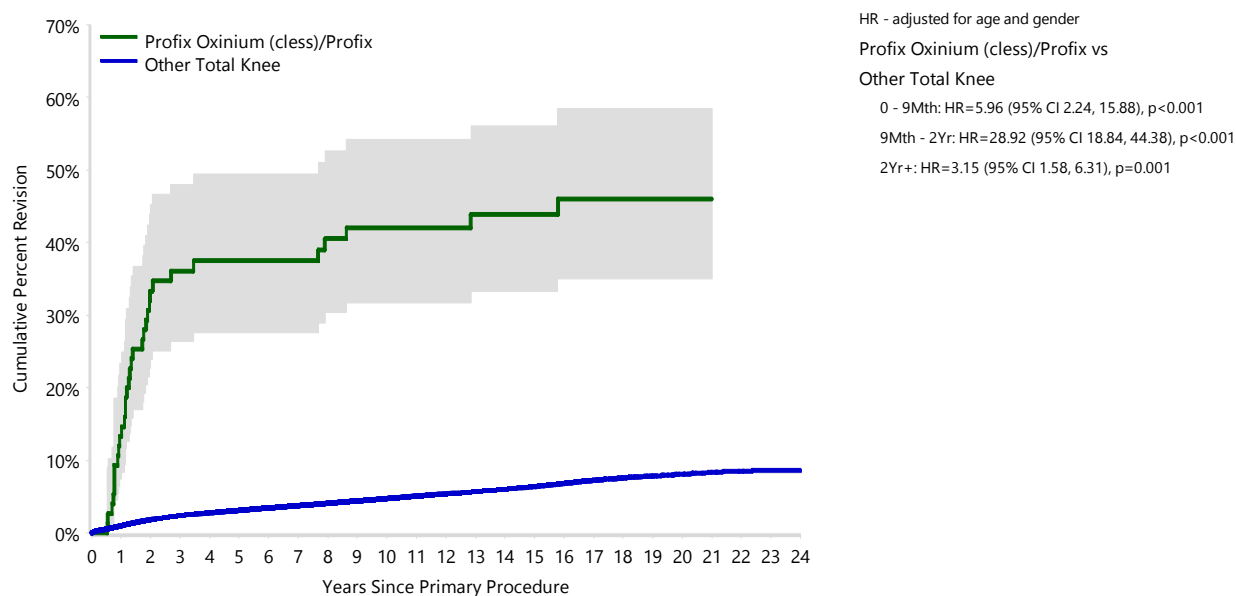
FIGURE 1

### Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Profix Oxinium (cless)/Profix total knee combination is compared to all other total knee prostheses. In addition, hazard ratios are reported.

Hazard ratios are reported for specific time periods during which the hazard ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

**Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement**



| Number at Risk                | 0 Yr   | 1 Yr   | 2 Yrs  | 3 Yrs  | 4 Yrs  | 5 Yrs  | 6 Yrs  | 7 Yrs  | 8 Yrs  | 9 Yrs  | 10 Yrs | 11 Yrs |
|-------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Profix Oxinium (cless)/Profix | 75     | 65     | 50     | 46     | 45     | 45     | 44     | 42     | 39     | 37     | 36     | 35     |
| Other Total Knee              | 721061 | 640728 | 562035 | 498192 | 435325 | 380214 | 326275 | 276480 | 231477 | 191174 | 154582 | 123868 |

| Number at Risk                | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs | 17 Yrs | 18 Yrs | 19 Yrs | 20 Yrs | 21 Yrs | 22 Yrs | 23 Yrs |
|-------------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Profix Oxinium (cless)/Profix | 32     | 30     | 29     | 29     | 25     | 24     | 22     | 22     | 18     | 16     | 6      | 0      |
| Other Total Knee              | 97988  | 75221  | 56549  | 41508  | 30003  | 21223  | 14967  | 10421  | 6807   | 4051   | 2359   | 1090   |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**TABLE 3****Primary Diagnosis for Revised Primary Total Knee Replacement**

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all other total knee prostheses.

**Table 3: Primary Diagnosis for Revised Primary Total Knee Replacement**

| Primary Diagnosis            | Profix Oxinium (class)/Profix |              | Other Total Knee |              |
|------------------------------|-------------------------------|--------------|------------------|--------------|
|                              | Number                        | Percent      | Number           | Percent      |
| Osteoarthritis               | 31                            | 93.9         | 23890            | 96.7         |
| Rheumatoid Arthritis         | 1                             | 3.0          | 301              | 1.2          |
| Tumour                       |                               |              | 192              | 0.8          |
| Other Inflammatory Arthritis | 1                             | 3.0          | 158              | 0.6          |
| Osteonecrosis                |                               |              | 90               | 0.4          |
| Fracture                     |                               |              | 50               | 0.2          |
| Other                        |                               |              | 25               | 0.1          |
| Chondrocalcinosis            |                               |              | 1                | 0.0          |
| <b>TOTAL</b>                 | <b>33</b>                     | <b>100.0</b> | <b>24707</b>     | <b>100.0</b> |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

TABLE 4

## Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

**% Primaries Revised:** This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

**% Revisions:** The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Primary Total Knee Replacement - Reason for Revision (Follow-up Limited to 22.2 Years)

| Revision Diagnosis             | Profix Oxinium (class)/Profix |                     |              | Other Total Knee |                     |              |
|--------------------------------|-------------------------------|---------------------|--------------|------------------|---------------------|--------------|
|                                | Number                        | % Primaries Revised | % Revisions  | Number           | % Primaries Revised | % Revisions  |
| Infection                      | 1                             | 1.3                 | 3.0          | 7091             | 1.0                 | 28.7         |
| Loosening                      | 28                            | 37.3                | 84.8         | 5261             | 0.7                 | 21.3         |
| Instability                    | 1                             | 1.3                 | 3.0          | 2537             | 0.4                 | 10.3         |
| Patella Erosion                |                               |                     |              | 1817             | 0.3                 | 7.4          |
| Pain                           |                               |                     |              | 1763             | 0.2                 | 7.1          |
| Patellofemoral Pain            |                               |                     |              | 1480             | 0.2                 | 6.0          |
| Arthrofibrosis                 | 1                             | 1.3                 | 3.0          | 1047             | 0.1                 | 4.2          |
| Fracture                       |                               |                     |              | 1017             | 0.1                 | 4.1          |
| Malalignment                   |                               |                     |              | 488              | 0.1                 | 2.0          |
| Wear Tibial Insert             |                               |                     |              | 322              | 0.0                 | 1.3          |
| Lysis                          | 1                             | 1.3                 | 3.0          | 264              | 0.0                 | 1.1          |
| Incorrect Sizing               |                               |                     |              | 210              | 0.0                 | 0.8          |
| Implant Breakage Tibial Insert |                               |                     |              | 204              | 0.0                 | 0.8          |
| Patella Maltracking            |                               |                     |              | 175              | 0.0                 | 0.7          |
| Bearing Dislocation            |                               |                     |              | 142              | 0.0                 | 0.6          |
| Implant Breakage Patella       |                               |                     |              | 132              | 0.0                 | 0.5          |
| Metal Related Pathology        |                               |                     |              | 101              | 0.0                 | 0.4          |
| Prosthesis Dislocation         |                               |                     |              | 70               | 0.0                 | 0.3          |
| Synovitis                      |                               |                     |              | 59               | 0.0                 | 0.2          |
| Osteonecrosis                  |                               |                     |              | 46               | 0.0                 | 0.2          |
| Implant Breakage Femoral       | 1                             | 1.3                 | 3.0          | 45               | 0.0                 | 0.2          |
| Wear Patella                   |                               |                     |              | 43               | 0.0                 | 0.2          |
| Implant Breakage Tibial        |                               |                     |              | 35               | 0.0                 | 0.1          |
| Tumour                         |                               |                     |              | 30               | 0.0                 | 0.1          |
| Heterotopic Bone               |                               |                     |              | 14               | 0.0                 | 0.1          |
| Progression Of Disease         |                               |                     |              | 8                | 0.0                 | 0.0          |
| Wear Tibial                    |                               |                     |              | 6                | 0.0                 | 0.0          |
| Incorrect Side                 |                               |                     |              | 1                | 0.0                 | 0.0          |
| Patella Dislocation            |                               |                     |              | 1                | 0.0                 | 0.0          |
| Wear Femoral                   |                               |                     |              | 1                | 0.0                 | 0.0          |
| Other                          |                               |                     |              | 296              | 0.0                 | 1.2          |
| <b>N Revision</b>              | <b>33</b>                     | <b>44.0</b>         | <b>100.0</b> | <b>24706</b>     | <b>3.4</b>          | <b>100.0</b> |
| <b>N Primary</b>               | <b>75</b>                     |                     |              | <b>721061</b>    |                     |              |

Note: This table is restricted to revisions within 22.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**FIGURE 2****Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement**

This figure details the cumulative incidence of the most common reasons for revision. The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the Profix Oxinium (cless)/Profix total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.

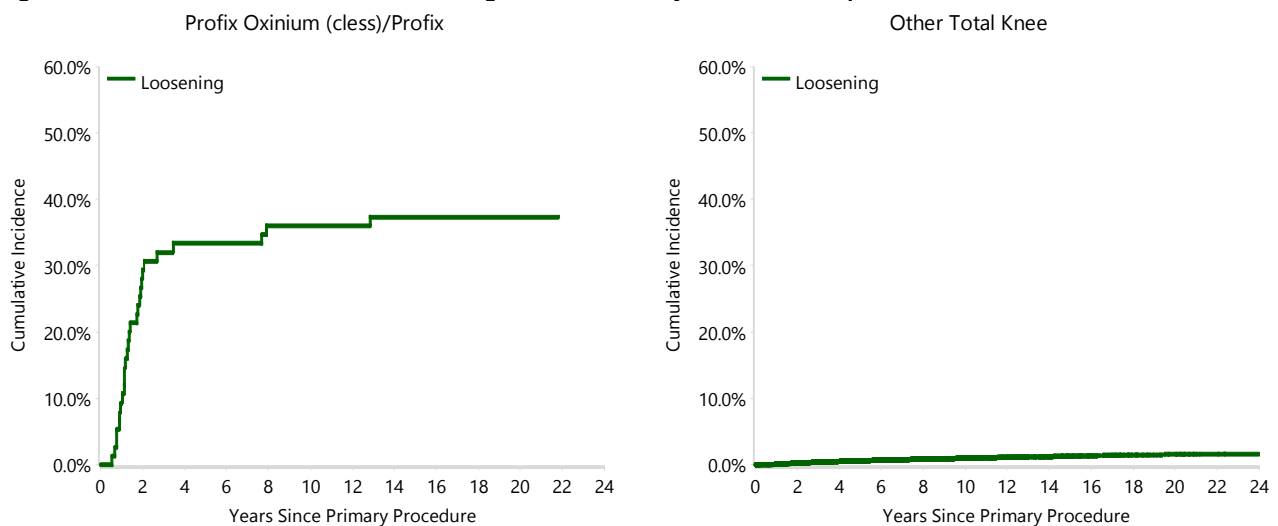
**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Knee Replacement**

TABLE 5

**Type of Revision Performed for Primary Total Knee Replacement**

This analysis identifies the components used in the revision of the Profix Oxinium (cless)/Profix total knee combination and compares it to the components used in the revision of all other total knee prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all other total knee prostheses i.e. is there a difference in the type of revision undertaken for the Profix Oxinium (cless)/Profix total knee combination compared to all other total knee prostheses.

**Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 22.2 Years)**

| Type of Revision          | Profix Oxinium (cless)/Profix |              | Other Total Knee |              |
|---------------------------|-------------------------------|--------------|------------------|--------------|
|                           | Number                        | Percent      | Number           | Percent      |
| TKR (Tibial/Femoral)      | 5                             | 15.2         | 5911             | 23.9         |
| Tibial Component          |                               |              | 1803             | 7.3          |
| Femoral Component         | 25                            | 75.8         | 1184             | 4.8          |
| Cement Spacer             |                               |              | 1082             | 4.4          |
| Removal of Prostheses     |                               |              | 126              | 0.5          |
| Total Femoral             |                               |              | 22               | 0.1          |
| Reinsertion of Components |                               |              | 7                | 0.0          |
| <b>N Major</b>            | <b>30</b>                     | <b>90.9</b>  | <b>10135</b>     | <b>41.0</b>  |
| Insert Only               | 1                             | 3.0          | 7667             | 31.0         |
| Patella Only              | 1                             | 3.0          | 4164             | 16.9         |
| Insert/Patella            | 1                             | 3.0          | 2668             | 10.8         |
| Minor Components          |                               |              | 63               | 0.3          |
| Cement Only               |                               |              | 9                | 0.0          |
| <b>N Minor</b>            | <b>3</b>                      | <b>9.1</b>   | <b>14571</b>     | <b>59.0</b>  |
| <b>TOTAL</b>              | <b>33</b>                     | <b>100.0</b> | <b>24706</b>     | <b>100.0</b> |

Note: This table is restricted to revisions within 22.2 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**TABLE 6****Revision Rates of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Fixation**

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

**Table 6: Revised Number of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Fixation**

| Fixation                 | N Revised | N Total   |
|--------------------------|-----------|-----------|
| Cementless               | 25        | 53        |
| Hybrid (Tibial Cemented) | 8         | 22        |
| <b>TOTAL</b>             | <b>33</b> | <b>75</b> |

**TABLE 7****Revision Rates of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Bearing Surface**

This analysis is provided as some prostheses are combined with a variety of bearing surfaces. All bearing surfaces used with this combination are listed.

**Table 7: Revised Number of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Bearing Surface**

| Bearing Surface | N Revised | N Total   |
|-----------------|-----------|-----------|
| Non XLPE        | 33        | 75        |
| <b>TOTAL</b>    | <b>33</b> | <b>75</b> |



**TABLE 8****Revision Rates of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Bearing Mobility**

This analysis is provided as some prostheses are combined with a variety of bearing mobilities. All bearing mobilities used with this combination are listed.

**Table 8: Revised Number of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Bearing Mobility**

| Bearing Mobility | N Revised | N Total   |
|------------------|-----------|-----------|
| Fixed            | 33        | 75        |
| <b>TOTAL</b>     | <b>33</b> | <b>75</b> |

**TABLE 9****Revision Rates of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Stability**

This analysis is provided as some prostheses are combined with a variety of stabilities. All stabilities used with this combination are listed.

**Table 9: Revised Number of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Stability**

| Stability            | N Revised | N Total   |
|----------------------|-----------|-----------|
| Minimally Stabilised | 33        | 75        |
| <b>TOTAL</b>         | <b>33</b> | <b>75</b> |

TABLE 10

**Revision Rates of Primary Total Knee Replacement by State**

This enables a state by state variation to be identified for the Profix Oxinium (cless)/Profix total knee combination and provides the comparative data for each of the states for all other total knee prostheses.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between states. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of states it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

**Table 10: Revised Number of Primary Total Knee Replacement by State**

| Component                     | State  | N Revised    | N Total       |
|-------------------------------|--------|--------------|---------------|
| Profix Oxinium (cless)/Profix | NSW    | 13           | 27            |
|                               | VIC    | 2            | 5             |
|                               | QLD    | 1            | 3             |
|                               | WA     | 0            | 2             |
|                               | SA     | 16           | 32            |
|                               | TAS    | 0            | 3             |
|                               | ACT/NT | 1            | 3             |
| Other Total Knee              | NSW    | 6834         | 236304        |
|                               | VIC    | 5457         | 148735        |
|                               | QLD    | 5317         | 152558        |
|                               | WA     | 3259         | 85158         |
|                               | SA     | 2886         | 66544         |
|                               | TAS    | 390          | 13242         |
|                               | ACT/NT | 564          | 18520         |
| <b>TOTAL</b>                  |        | <b>24740</b> | <b>721136</b> |

Note: Prostheses no longer used in 2024 are excluded from the comparator.

**TABLE 11****Number of Revisions of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Profix Oxinium (cless)/Profix total knee combination. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 has a maximum of three years to be revised.

**Table 11: Number of Revisions of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Year of Implant**

| Year of Implant | Number Revised | Total Number |
|-----------------|----------------|--------------|
| 2002            | 3              | 10           |
| 2003            | 30             | 65           |
| <b>TOTAL</b>    | <b>33</b>      | <b>75</b>    |

TABLE 12

**Revision Rates of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Catalogue Number Range**

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular Profix Oxinium (cless)/Profix prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

| Model          | Catalogue Range   | Catalogue Description                          | Cement | Coating   | Fixation      |
|----------------|-------------------|------------------------------------------------|--------|-----------|---------------|
| <b>Femoral</b> |                   |                                                |        |           |               |
| Profix Oxinium | 71502127-71502277 | PROFIX OXINIUM MACROTEXTURED FEMORAL COMPONENT | NO     |           | MACROTEXTURED |
| <b>Tibial</b>  |                   |                                                |        |           |               |
| Profix         | 71504110-71504270 | POROUS TIBIAL BASEPLATE                        | NO     |           | POROUS        |
| Profix         | 71504151-71504261 | POROUS TIBIAL BASEPLATE W.OUT/HOLES            | NO     |           | POROUS        |
| Profix         | 71505320-71505460 | POROUS HA TIBIAL BASEPLATE W.OUT/HOLES         | NO     | HA COATED | POROUS        |
| Profix         | 71524110-71524270 | NONPOROUS TIBIAL BASEPLATE                     | YES    |           |               |
| Profix         | 71926278-71926299 | POROUS HA TIBIAL BASEPLATE W.OUT/HOLES         | NO     | HA COATED | POROUS        |

**Table 12: Revised Number of Profix Oxinium (cless)/Profix Primary Total Knee Replacement by Catalogue Number Range**

| Femoral Range     | Tibial Range      | N Revised | N Total   |
|-------------------|-------------------|-----------|-----------|
| 71502127-71502277 | 71504110-71504270 | 3         | 9         |
|                   | 71504151-71504261 | 0         | 1         |
|                   | 71505320-71505460 | 2         | 3         |
|                   | 71524110-71524270 | 8         | 22        |
|                   | 71926278-71926299 | 20        | 40        |
| <b>TOTAL</b>      |                   | <b>33</b> | <b>75</b> |