# Bionik Total Conventional Hip Investigation

Note: This analysis compares the Bionik acetabular prosthesis with all other total conventional hip prostheses.

This prosthesis 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-2026.

Note: Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator. Procedures using prostheses with no recorded use in 2025 are excluded from the comparator.

## TABLE 1

### Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Bionik total conventional hip prosthesis is compared to all other total conventional hip prostheses.

### Table 1: Revision Rates of Primary Total Conventional Hip Replacement

| Component | N Revised | N Total | Obs. Years | Revisions/100 Obs. Yrs (95% CI) |
|---|---|---|---|---|
| Bionik | 160 | 608 | 6516 | 2.46 (2.09, 2.87) |
| Other Total Conventional Hip | 19701 | 568612 | 3623071 | 0.54 (0.54, 0.55) |
| **TOTAL** | **19861** | **569220** | **3629587** | **0.55 (0.54, 0.55)** |

Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 2

## Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Bionik total conventional hip prosthesis is compared to all other total conventional hip prostheses.

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

| CPR | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs |
|---|---|---|---|---|---|---|
| Bionik | 3.6 (2.4, 5.5) | 5.3 (3.8, 7.4) | 7.7 (5.8, 10.2) | 10.9 (8.6, 13.7) | 14.3 (11.7, 17.5) | 17.0 (14.1, 20.3) |
| Other Total Conventional Hip | 1.7 (1.7, 1.8) | 2.1 (2.1, 2.2) | 2.5 (2.4, 2.5) | 2.8 (2.7, 2.8) | 3.0 (3.0, 3.1) | 3.3 (3.2, 3.3) |

| CPR | 7 Yrs | 8 Yrs | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs |
|---|---|---|---|---|---|---|
| Bionik | 19.9 (16.8, 23.5) | 22.1 (18.9, 25.8) | 23.2 (19.9, 27.0) | 24.3 (20.9, 28.2) | 26.5 (22.9, 30.5) | 28.3 (24.6, 32.5) |
| Other Total Conventional Hip | 3.5 (3.5, 3.6) | 3.8 (3.7, 3.9) | 4.1 (4.0, 4.2) | 4.4 (4.3, 4.5) | 4.7 (4.6, 4.8) | 5.1 (5.0, 5.2) |

| CPR | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs | 17 Yrs | 18 Yrs |
|---|---|---|---|---|---|---|
| Bionik | 29.4 (25.6, 33.6) | 30.0 (26.1, 34.3) | 30.6 (26.7, 34.9) | 30.6 (26.7, 34.9) | 31.0 (27.0, 35.4) | 31.0 (27.0, 35.4) |
| Other Total Conventional Hip | 5.4 (5.3, 5.5) | 5.8 (5.7, 5.9) | 6.2 (6.1, 6.3) | 6.6 (6.5, 6.7) | 7.0 (6.8, 7.1) | 7.3 (7.1, 7.5) |

| CPR | 19 Yrs | 20 Yrs | 21 Yrs | 22 Yrs | 23 Yrs | 24 Yrs | 25 Yrs |
|---|---|---|---|---|---|---|---|
| Bionik | 33.3 (28.4, 38.8) | | | | | | |
| Other Total Conventional Hip | 7.7 (7.5, 7.9) | 8.0 (7.8, 8.2) | 8.6 (8.3, 8.9) | 9.0 (8.7, 9.4) | 9.6 (9.1, 10.0) | 9.6 (9.2, 10.1) | 10.3 (9.4, 11.2) |

Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

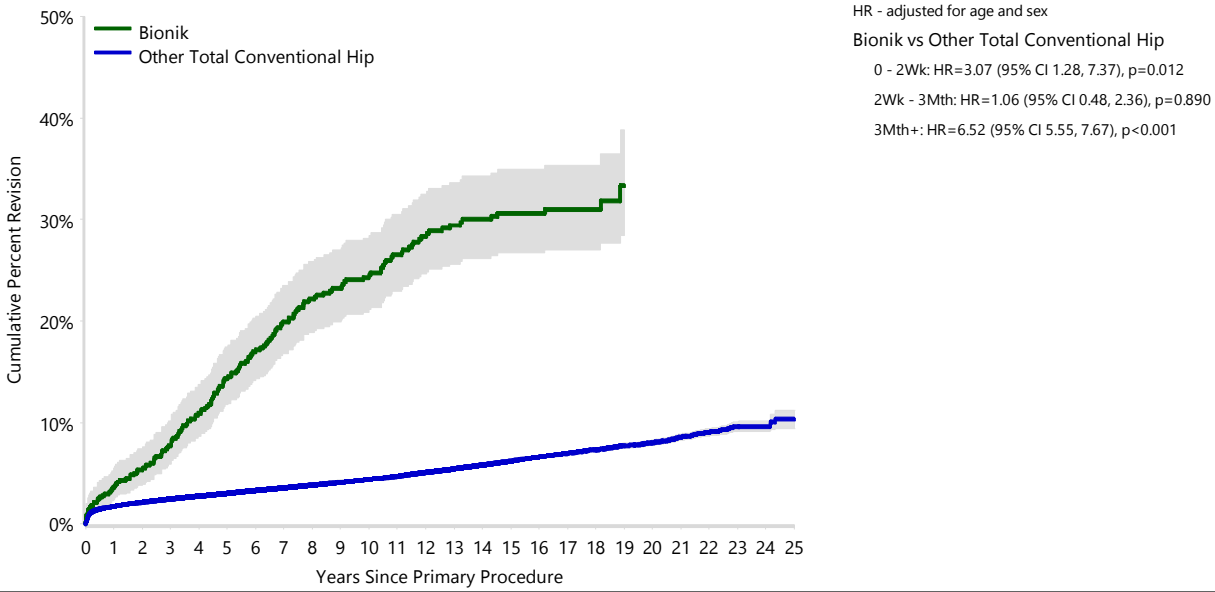
FIGURE 1

## Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the Bionik total conventional hip prosthesis is compared to all other total conventional hip 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 Conventional Hip Replacement




| Number at Risk | 0 Yr | 1 Yr | 2 Yrs | 3 Yrs | 4 Yrs | 5 Yrs | 6 Yrs | 7 Yrs |
|---|---|---|---|---|---|---|---|---|
| Bionik | 608 | 579 | 554 | 531 | 499 | 465 | 434 | 403 |
| Other Total Conventional Hip | 568612 | 501603 | 445433 | 391564 | 344389 | 299354 | 259516 | 220948 |

| Number at Risk | 8 Yrs | 9 Yrs | 10 Yrs | 11 Yrs | 12 Yrs | 13 Yrs | 14 Yrs | 15 Yrs | 16 Yrs |
|---|---|---|---|---|---|---|---|---|---|
| Bionik | 375 | 351 | 320 | 290 | 269 | 251 | 233 | 215 | 185 |
| Other Total Conventional Hip | 185798 | 153739 | 124848 | 99575 | 79802 | 63343 | 49730 | 38033 | 28355 |

| Number at Risk | 17 Yrs | 18 Yrs | 19 Yrs | 20 Yrs | 21 Yrs | 22 Yrs | 23 Yrs | 24 Yrs | 25 Yrs |
|---|---|---|---|---|---|---|---|---|---|
| Bionik | 136 | 85 | 40 | 3 | 0 | 0 | 0 | 0 | 0 |
| Other Total Conventional Hip | 20437 | 14638 | 10400 | 7396 | 4859 | 2863 | 1455 | 560 | 95 |

Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 3

## Primary Diagnosis for Revised Primary Total Conventional Hip 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 conventional hip prostheses.

### Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement

| | Bionik | | Other Total Conventional Hip | |
|---|---|---|---|---|
| Primary Diagnosis | Number | Percent | Number | Percent |
| Osteoarthritis | 144 | 90.0 | 16296 | 82.7 |
| Fractured Neck Of Femur | 5 | 3.1 | 1521 | 7.7 |
| Osteonecrosis | 5 | 3.1 | 844 | 4.3 |
| Developmental Dysplasia | 1 | 0.6 | 321 | 1.6 |
| Rheumatoid Arthritis | 2 | 1.3 | 201 | 1.0 |
| Failed Internal Fixation | 1 | 0.6 | 165 | 0.8 |
| Tumour | | | 157 | 0.8 |
| Other Inflammatory Arthritis | 2 | 1.3 | 102 | 0.5 |
| Fracture/Dislocation | | | 60 | 0.3 |
| Other | | | 21 | 0.1 |
| Arthrodesis Takedown | | | 13 | 0.1 |
| **TOTAL** | **160** | **100.0** | **19701** | **100.0** |

Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm 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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 20.4 Years)

| | Bionik | | | Other Total Conventional Hip | | |
|---|---|---|---|---|---|---|
| Revision Diagnosis | Number | % Primaries Revised | % Revisions | Number | % Primaries Revised | % Revisions |
| Infection | 26 | 4.3 | 16.3 | 5010 | 0.9 | 25.5 |
| Prosthesis Dislocation/Instability | 20 | 3.3 | 12.5 | 4379 | 0.8 | 22.3 |
| Fracture | 6 | 1.0 | 3.8 | 4338 | 0.8 | 22.1 |
| Loosening | 34 | 5.6 | 21.3 | 3613 | 0.6 | 18.4 |
| Pain | 6 | 1.0 | 3.8 | 339 | 0.1 | 1.7 |
| Leg Length Discrepancy | 1 | 0.2 | 0.6 | 307 | 0.1 | 1.6 |
| Malposition | 2 | 0.3 | 1.3 | 282 | 0.0 | 1.4 |
| Implant Breakage Stem | 1 | 0.2 | 0.6 | 208 | 0.0 | 1.1 |
| Lysis | 15 | 2.5 | 9.4 | 196 | 0.0 | 1.0 |
| Implant Breakage Acetabular Insert | 1 | 0.2 | 0.6 | 126 | 0.0 | 0.6 |
| Wear Acetabular Insert | 2 | 0.3 | 1.3 | 106 | 0.0 | 0.5 |
| Incorrect Sizing | | | | 96 | 0.0 | 0.5 |
| Metal Related Pathology | 41 | 6.7 | 25.6 | 90 | 0.0 | 0.5 |
| Implant Breakage Acetabular | 3 | 0.5 | 1.9 | 73 | 0.0 | 0.4 |
| Wear Head | | | | 48 | 0.0 | 0.2 |
| Tumour | | | | 46 | 0.0 | 0.2 |
| Heterotopic Bone | | | | 26 | 0.0 | 0.1 |
| Implant Breakage Head | | | | 26 | 0.0 | 0.1 |
| Wear Acetabulum | | | | 6 | 0.0 | 0.0 |
| Osteonecrosis | | | | 4 | 0.0 | 0.0 |
| Synovitis | | | | 2 | 0.0 | 0.0 |
| Progression Of Disease | | | | 1 | 0.0 | 0.0 |
| Other | 2 | 0.3 | 1.3 | 321 | 0.1 | 1.6 |
| **N Revision** | **160** | **26.3** | **100.0** | **19643** | **3.5** | **100.0** |
| **N Primary** | **608** | | | **568612** | | |

Note: This table is restricted to revisions within 20.4 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

FIGURE 2

## Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip 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 Bionik total conventional hip prosthesis. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total conventional hip prostheses.

### Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement

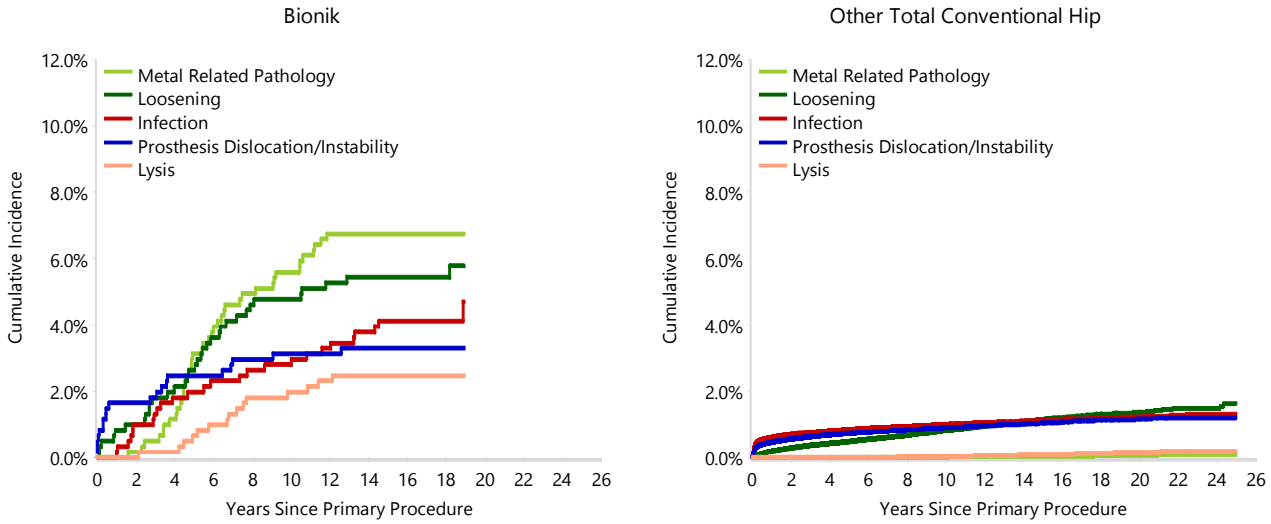


TABLE 5

## Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Bionik total conventional hip prosthesis and compares it to the components used in the revision of all other total conventional hip 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 conventional hip prostheses i.e. is there a difference in the type of revision undertaken for the Bionik total conventional hip prosthesis compared to all other total conventional hip prostheses.

**Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 20.4 Years)**

| | Bionik | | Other Total Conventional Hip | |
|---|---|---|---|---|
| Type of Revision | Number | Percent | Number | Percent |
| Femoral Component | 19 | 11.9 | 6633 | 33.8 |
| Acetabular Component | 46 | 28.8 | 3297 | 16.8 |
| THR (Femoral/Acetabular) | 35 | 21.9 | 2288 | 11.6 |
| Cement Spacer | 7 | 4.4 | 556 | 2.8 |
| Removal of Prostheses | | | 92 | 0.5 |
| Reinsertion of Components | | | 27 | 0.1 |
| Total Femoral | | | 12 | 0.1 |
| Bipolar Head and Femoral | | | 10 | 0.1 |
| **N Major** | **107** | **66.9** | **12915** | **65.7** |
| Head/Insert | 4 | 2.5 | 5360 | 27.3 |
| Head Only | 1 | 0.6 | 912 | 4.6 |
| Minor Components | 3 | 1.9 | 285 | 1.5 |
| Insert Only | 1 | 0.6 | 168 | 0.9 |
| Head/Neck/Insert | 39 | 24.4 | 1 | 0.0 |
| Head/Neck | 5 | 3.1 | | |
| Bipolar Only | | | 1 | 0.0 |
| Cement Only | | | 1 | 0.0 |
| **N Minor** | **53** | **33.1** | **6728** | **34.3** |
| **TOTAL** | **160** | **100.0** | **19643** | **100.0** |

Note: This table is restricted to revisions within 20.4 years for all groups to allow a time-matched comparison of revisions.
Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

## TABLE 6

### Revision Rates of Bionik Primary Total Conventional Hip 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 Bionik Primary Total Conventional Hip Replacement by Fixation

| Fixation | N Revised | N Total |
|---|---|---|
| Cemented | 1 | 2 |
| Cementless | 132 | 521 |
| Hybrid (Femur Cemented) | 27 | 84 |
| Reverse Hybrid (Femur Cementless) | 0 | 1 |
| **TOTAL** | **160** | **608** |

## TABLE 7

### Revision Rates of Bionik Primary Total Conventional Hip 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 prosthesis are listed.

### Table 7: Revised Number of Bionik Primary Total Conventional Hip Replacement by Bearing Surface

| Bearing Surface | N Revised | N Total |
|---|---|---|
| Ceramic/Ceramic | 5 | 9 |
| Ceramic/Non XLPE | 8 | 45 |
| Metal/Metal | 111 | 425 |
| Metal/Non XLPE | 36 | 129 |
| **TOTAL** | **160** | **608** |

## TABLE 8

### Revision Rates of Primary Total Conventional Hip Replacement by State

This enables a state by state variation to be identified for the Bionik total conventional hip prosthesis and provides the comparative data for each of the states for all other total conventional hip 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 8: Revised Number of Primary Total Conventional Hip Replacement by State**

| Component | State | N Revised | N Total |
|---|---|---|---|
| Bionik | NSW | 78 | 326 |
| | VIC | 18 | 87 |
| | QLD | 7 | 19 |
| | WA | 16 | 34 |
| | SA | 1 | 5 |
| | TAS | 40 | 136 |
| | ACT/NT | 0 | 1 |
| Other Total Conventional Hip | NSW | 5507 | 167002 |
| | VIC | 4853 | 146558 |
| | QLD | 3968 | 104359 |
| | WA | 2510 | 64946 |
| | SA | 1887 | 52084 |
| | TAS | 439 | 18269 |
| | ACT/NT | 537 | 15394 |
| **TOTAL** | | **19861** | **569220** |

Note: Prostheses no longer used in 2025 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 9

## Number of Revisions of Bionik Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Bionik total conventional hip prosthesis. 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 2025 has a maximum of one year to be revised, whereas a primary procedure performed in 2023 has a maximum of three years to be revised.

### Table 9: Number of Revisions of Bionik Primary Total Conventional Hip Replacement by Year of Implant

| Year of Implant | Number Revised | Total Number |
|---|---|---|
| 2005 | 3 | 11 |
| 2006 | 42 | 147 |
| 2007 | 31 | 136 |
| 2008 | 31 | 138 |
| 2009 | 35 | 134 |
| 2010 | 18 | 38 |
| 2011 | 0 | 4 |
| **TOTAL** | **160** | **608** |

TABLE 10

## Revision Rates of Bionik Primary Total Conventional Hip 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 Bionik 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 | Material |
|---|---|---|---|---|
| **Acetabular** | | | | |
| Bionik | 10201050-10201064 | METAL SHELL BS TINB COAT | NO | METAL |
| Bionik | 10201150-10201164 | METAL SHELL BS TINB COAT SCREW FIX | NO | METAL |
| Bionik | 10201246-10201264 | METAL SHELL CEMENTLESS TINB COAT SCREW FIX | NO | METAL |
| Bionik | 10201346-10201366 | METAL SHELL TINB CAP SCREW FIX | NO | METAL |
| Bionik | 10202154-10202164 | METAL SHELL CEMENTLESS DYSPL. TINB C. SCREW FIX | NO | METAL |

### Table 10: Revised Number of Bionik Primary Total Conventional Hip Replacement by Catalogue Number Range

| Acetabular Range | N Revised | N Total |
|---|---|---|
| 10201050-10201064 | 8 | 23 |
| 10201150-10201164 | 44 | 138 |
| 10201246-10201264 | 13 | 63 |
| 10201346-10201366 | 94 | 381 |
| 10202154-10202164 | 1 | 3 |
| **TOTAL** | **160** | **608** |

## TABLE 11

### Revision Rates of Bionik Primary Total Conventional Hip Replacement by Component

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

**Table 11: Revised Number of Bionik Primary Total Conventional Hip Replacement by Femoral Stem Component**

| Femoral Stem Component | N Revised | N Total |
|---|---|---|
| Adapter (cless) | 138 | 527 |
| Adapter (ctd) | 20 | 72 |
| CORAIL | 1 | 1 |
| Custom Made (Eska) | 0 | 1 |
| Edinburgh | 0 | 1 |
| GHE | 0 | 4 |
| K2 | 1 | 1 |
| S-Rom | 0 | 1 |
| **TOTAL** | **160** | **608** |