

Orthopaedic appliances in Belgium Health Technology Assessment supplements

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The Belgian Health Care Knowledge Centre

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Orthopaedic material in Belgium - supplements

KCE reports 56S

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Conflict of interest : One expert, who is the director of an enterprise, notified that the enterprise "OTTO BOCK" is one of his company's stakeholders. One expert has worked as an orthotist until 2006 and now gives lectures on the topic.

Disclaimer: The experts and validators collaborated on the scientific report, but are not responsible for the policy recommendations. These recommendations are under the full responsibility of the Belgian Health Care Knowledge Centre.

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APPENDICES

APPENDIX TO CHAPTER I

All orthotic devices in NECK, WRIST AND KNEE brace categories (RIZIV/INAMI billing codes)

| Type Orthese | RIZIV code | Main Category | Subcategory | Label_NL |
|--------------|------------|--------------------------|-------------|--|
| HALS | 645234 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Stijve halskraag met kin- en/of achterhoofdsteun, niet regelbaar in de hoogte |
| | 645315 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab : Cervicaal Tractiesysteem, volledig met Glissonse lus, juk, tractie- en bevestigingssysteem, gewichtscontainer en alle nodige productattributen |
| | 645293 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab : Halo Brace, (Halo ring met verbandsstructuur, vest, binnenvest en alle nodige produktattributen) |
| | 645094 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Maatwerk - Vooraan : mandibulae gedeeltelijk omsluitend tot manubrium sterni ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 3 ; Opzij : rustend tot op de schouders : Minerva halskraag in plastic |
| | 645256 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : mandibulae gedeeltelijk omsluitend tot manubrium sterni ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 3 ; Opzij : rustend tot op de schouders : Al dan niet regelbare halskraag met thoraxsteun, type minerva |
| | 645116 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Maatwerk - Vooraan : mandibulae gedeeltelijk omsluitend tot manubrium sterni ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 3 ; Opzij : rustend tot op de schouders : Minerva halskraag in leder |
| | 645153 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Maatwerk - Vooraan : mandibulae gedeeltelijk omsluitend tot processus ensiformis ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 10 ; Opzij : rustend tot op de schouders : Minerva met thoraxcorselet in leder |
| | 645212 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Stijve halskraag met kin- en/of achterhoofdsteun, regelbaar in de hoogte |
| | 645190 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Stijve halskraag, al dan niet regelbaar in de hoogte |
| | 645131 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Maatwerk - Vooraan : mandibulae gedeeltelijk omsluitend tot processus ensiformis ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 10 ; Opzij : rustend tot op de schouders : Minerva met thoraxcorselet in plastic |
| | 645271 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : manibulae gedeeltelijk omsluitend tot processus ensiformis ; Achteraan : vanaf onderste derde van de ossa parietalia tot D 10 ; Opzij : rustend tot op de schouders : Halskraag, type minerva met thoraxsteun |
| | 645072 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Maatwerk - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Halskraag van het Schanz-type met |

| Type Orthese | RIZIV code | Main Category | Subcategory | Label_NL |
|--------------|------------|-----------------------------|--------------------------|--|
| | | | | kinsteun, in gevormd leder of gevormd plastic |
| | 645175 | Orthesen Hoofd-Hals-Romp | Hals | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Soepele halskraag |
| POLS | 649375 | Orthesen Bovenste Ledematen | Handpalm en vingers | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep III : Handpalm en vinger(s) - Van het uiteinde der vingers, met ten minste één vinger tot aan het metacarpocarpaal gewricht - Prefab - Hand- en vingerorth |
| | 649331 | Orthesen Bovenste Ledematen | Handpalm en vingers | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep III : Handpalm en vinger(s) - Van het uiteinde der vingers, met ten minste één vinger tot aan het metacarpocarpaal gewricht - Maatwerk - Hand- en vingerse |
| | 649412 | Orthesen Bovenste Ledematen | Pols | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep IV : Pols - Van midden metacarpaal tot 1/3 proximaal van het polsgewricht - Prefab : Licht bewegingsbeperkende polsbandage met lusband voor bijkomende ste |
| | 649530 | Orthesen Bovenste Ledematen | Hand pols en onderarm | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep VI : Hand - pols en onderarm - Van het metacarpophalangeaal gewricht, reikend tot proximaal twee derden van de onderarm. De lengte van de onderearm word |
| | 649552 | Orthesen Bovenste Ledematen | Hand pols en onderarm | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep VI : Hand - pols en onderarm - Van het metacarpophalangeaal gewricht, reikend tot proximaal twee derden van de onderarm. De lengte van de onderearm word |
| | 649390 | Orthesen Bovenste Ledematen | Handpalm en vingers | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep III : Handpalm en vinger(s) - Van het uiteinde der vingers, met ten minste één vinger tot aan het metacarpocarpaal gewricht - IMF - Hand- en vingersegment |
| | 649434 | Orthesen Bovenste Ledematen | Pols | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep IV : Pols - Van midden metacarpaal tot 1/3 proximaal van het polsgewricht - Prefab : Sterk bewegingsbeperkende polsbandage met harde verstijving |
| | 649353 | Orthesen Bovenste Ledematen | Handpalm en vingers | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep III : Handpalm en vinger(s) - Van het uiteinde der vingers, met ten minste één vinger tot aan het metacarpocarpaal gewricht - Prefab - Hand- en vingerorth |
| | 649795 | Orthesen Bovenste Ledematen | Hand, onderarm, bovenarm | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep X : Hand - onderarm - bovenarm - Van de handpalm tot de helft van de bovenarm. De meetpunten zijn de elleboog- en de okselplooi - Prefab - Hand-, onder |
| KNIE | 655690 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647356 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk : Toestel dij en been, elk toestel |
| | 647393 | Orthesen onderste | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniesplee |

| Type Orthese | RIZIV code | Main Category | Subcategory | Label_NL |
|--------------|------------|-----------------------------------|-------------|---|
| | | ledematen | | |
| | 647496 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk : Bijslag voor kniegeleding |
| | 647474 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk : Bijslag voor hielgreep |
| | 647452 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk : Bijslag voor beugel |
| | 647570 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647555 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab : Kniestuk, soepel geweve, al dan niet met neopreen, verstevigd met baleinen |
| | 647592 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647614 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647371 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647533 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab : Kniestuk uit stof of elastisch weefsel of neopreen met metalen versterking, geled aan de knie, geprefabriceerd model met individueel |
| | 647430 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647415 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet |
| | 647511 | Orthesen onderste ledematen | Knie | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Maatwerk : Bijslag per grendel en/of sector |

APPENDIX TO CHAPTER II

Literature searches

Table 1: Orthopedic Equipment MESH terms

| |
|-------------------------------------|
| Equipment and Supplies [E07] |
| Surgical Equipment [E07.858] |
| Orthopedic Equipment [E07.858.442] |
| Artificial Limbs [E07.858.442.050] |
| Canes [E07.858.442.250] |
| Crutches [E07.858.442.281] |
| Orthotic Devices [E07.858.442.743] |
| Braces [E07.858.442.743.319] |
| Walkers [E07.858.442.980] |

Table 2: PubMed Clinical Queries searches

| Queries | Search terms | Results |
|--------------|---|---------|
| Topic | Cervical | |
| #1 | (cervic* AND collar*) AND systematic[sb] | 9 |
| #2 | (cervic* AND collar*) AND (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract])) | 33 |
| Topic | Wrist | |
| #1 | (wrist* AND (splint* OR brace* or bracing*)) AND systematic[sb] | 27 |
| #2 | (wrist* AND (splint* OR brace* or bracing*)) AND (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract])) | 67 |
| Topic | Knee | |
| #1 | (knee brac*) AND systematic[sb] | 9 |
| #2 | (knee brac*) AND (randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract])) | 21 |

Table 3: Ovid-Medline searches (from <1966 to January Week 4 2007 + In-Process & Other Non-Indexed Citations)

| Queries | Search terms | Results |
|--------------|--|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=ti, ot, ab, nm, hw] | 138.633 |
| #2 | collar\$.mp. [mp=ti, ot, ab, nm, hw] | 4.736 |
| #3 | splint\$.mp. [mp=ti, ot, ab, nm, hw] | 11.609 |
| #4 | 2 or 3 | 16.320 |
| #5 | 1 and 4 | 710 |
| #6 | limit 5 to (clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline or randomized controlled trial) | 65 |
| #7 | systematic review.mp. | 9.033 |
| #8 | 6 or 7 | 9.098 |
| #9 | 5 and 8 | 65 |
| #10 | from 9 keep 1-2,4,9-11,14-15,17,23-24,26,30,33,36,38,40,43-47,51,56-57,59-65 | 32 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=ti, ot, ab, nm, hw] | 21.426 |
| #2 | splint\$.mp. [mp=ti, ot, ab, nm, hw] | 11.609 |
| #3 | brace\$.mp. [mp=ti, ot, ab, nm, hw] | 5.062 |
| #4 | bracing\$.mp. [mp=ti, ot, ab, nm, hw] | 1.349 |
| #5 | 2 or 3 or 4 | 17.081 |
| #6 | 1 and 5 | 659 |
| #7 | limit 6 to (clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline or randomized controlled trial) | 83 |
| #8 | systematic review.mp. [mp=ti, ot, ab, nm, hw] | 9.033 |
| #9 | 7 or 8 | 9.115 |
| #10 | 6 and 9 | 87 |
| #11 | from 10 keep 1-3,6-12,14-16,19-20,22,25,28-47,50,52-53,57-59,61-63,65-72,74-76,78-87 | 67 |
| Topic | Wrist | |
| #1 | knee\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (67388) | 68.388 |
| #2 | brace\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4982) | 4.982 |
| #3 | knee-ankle-foot orthos\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (75) | 75 |
| #4 | 1 and 2 (786) | 786 |
| #5 | 4 not 3 (755) | 755 |
| #6 | limit 5 to (clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline or randomized controlled trial) (91) | 91 |
| #7 | systematic review.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (8420) | 8.420 |
| #8 | 5 or 7 (3) | 3 |
| #9 | 6 and 8 (93) | 93 |
| #10 | from 9 keep 3-5,10,12-13,16-18,21-22,24-25,29,31,33-34,36,38-40,43-50,58,61-78,80-82,84,86-87,89,91,93 (57) | 57 |

Table 4: CRCT searches

| Queries | Search terms | Results |
|--------------|---|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 4.698 |
| #2 | collar\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 169 |
| #3 | splint\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 615 |
| #4 | 2 or 3 | 782 |
| #5 | 1 and 4 | 70 |
| #6 | laryngo\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 1.169 |
| #7 | 5 not 6 | 64 |
| #8 | from 7 keep 1-2,4,6-11,13-14,16,19-24,28-32,34-35,37-39,42-45,47-50,52,54-57,59-60,62-64 | 46 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 1.014 |
| #2 | splint\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 615 |
| #3 | brace\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 333 |
| #4 | bracing\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 91 |
| #5 | 2 or 3 or 4 | 961 |
| #6 | 1 and 5 | 72 |
| #7 | limit 6 to (clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline or randomized controlled trial) | 61 |
| | from 7 keep 1-3,7-9,11-20,22-23,25-29,31-34,36-50,52,54,56-58,60-61 | 49 |
| Topic | Knee | |
| #1 | knee\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 5.095 |
| | (5095) | |
| #2 | brace\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 333 |
| | (333) | |
| #4 | ankle\$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] | 2.045 |
| | (2045) | |
| #5 | 1 and 2 (91) | 91 |
| #6 | 5 not 4 (70) | 70 |
| #7 | from 6 keep 1-70 (70) | 70 |

Table 5: CDSR searches

| Queries | Search terms | Results |
|--------------|--|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=title, abstract, full text, keywords, caption text] | 388 |
| #2 | collar\$.mp. [mp=title, abstract, full text, keywords, caption text] | 37 |
| #3 | splint\$.mp. [mp=title, abstract, full text, keywords, caption text] | 104 |
| #4 | 2 or 3 | 137 |
| #5 | 1 and 4 | 22 |
| #6 | from 5 keep 4,6-8,10-12,15,17,20 | 10 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=title, abstract, full text, keywords, caption text] (123) | 123 |
| #2 | splint\$.mp. [mp=title, abstract, full text, keywords, caption text] (104) | 104 |
| #3 | brace\$.mp. [mp=title, abstract, full text, keywords, caption text] (74) | 74 |
| #4 | bracing\$.mp. [mp=title, abstract, full text, keywords, caption text] (30) | 30 |
| #5 | 2 or 3 or 4 (156) | 156 |
| #6 | 1 and 5 (40) | 40 |
| #7 | from 6 keep 1-2,7,9-11,13-14,16,18,23-24,27-28,32-33,36-37,39-40 (20) | 20 |
| Topic | Knee | |
| #1 | knee\$.mp. [mp=title, abstract, full text, keywords, caption text] | 243 |
| #2 | brace\$.mp. [mp=title, abstract, full text, keywords, caption text] | 74 |
| #3 | knee-ankle-foot orthos\$.mp. [mp=title, abstract, full text, keywords, caption text] | 1 |
| #4 | ankle\$.mp. [mp=title, abstract, full text, keywords, caption text] | 175 |
| #5 | 3 or 4 | 175 |
| #6 | 1 and 2 | 27 |
| #7 | 6 not 5 | 10 |
| #8 | from 7 keep 2,4-5,8,10 | 5 |

Table 6: DARE searches

| Queries | Search terms | Results |
|--------------|--|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=title, full text, keywords] | 148 |
| #2 | collar\$.mp. [mp=title, full text, keywords] | 14 |
| #3 | splint\$.mp. [mp=title, full text, keywords] | 31 |
| #4 | 2 or 3 | 45 |
| #5 | 1 and 4 | 6 |
| #6 | from 5 keep 1-4,6 | 5 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=title, full text, keywords] | 38 |
| #2 | splint\$.mp. [mp=title, full text, keywords] | 31 |
| #3 | brace\$.mp. [mp=title, full text, keywords] | 23 |
| #4 | bracing\$.mp. [mp=title, full text, keywords] | 11 |
| #5 | 2 or 3 or 4 | 57 |
| #6 | 1 and 5 | 7 |
| #7 | from 6 keep 1-7 | 7 |
| Topic | Knee | |
| #1 | knee\$.mp. [mp=title, full text, keywords] | 153 |
| #2 | brace\$.mp. [mp=title, full text, keywords] | 23 |
| #4 | knee-ankle-foot orthos\$.mp. [mp=title, full text, keywords] | 1 |
| #5 | ankle\$.mp. [mp=title, full text, keywords] | 54 |
| #6 | 3 or 4 | 54 |
| #7 | 1 and 2 (3) | 3 |
| #8 | 6 not 5 (2) | 2 |
| #9 | from 7 keep 1-2 (2) | 2 |

Table 7: CINAHL searches <1982 to December Week 2 2006>

| Queries | Search terms | Results |
|--------------|--|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 7.542 |
| #2 | collar\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 640 |
| #3 | splint\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 1.343 |
| #4 | 2 or 3 | 1.976 |
| #5 | 1 and 4 | 123 |
| #6 | limit 5 to (clinical trial or controlled clinical trial or meta analysis or multicenter study or practice guideline) | 6 |
| #7 | systematic review.mp. | 5.018 |
| #8 | 6 or 7 | 45 |
| #9 | 5 and 8 | 6 |
| #10 | from 9 keep 2,4,6 | 3 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 2.269 |
| #2 | splint\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 1.343 |
| #3 | brace\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 744 |
| #4 | bracing\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 399 |
| #5 | 2 or 3 or 4 | 2.298 |
| #6 | 1 and 5 | 222 |
| #7 | *Botulinum Toxins/tu [Therapeutic use] | 471 |
| #8 | 6 not 7 | 219 |
| #9 | tennis elbow.mp. [mp=title, subject heading word, abstract, instrumentation] | 388 |
| #10 | 8 not 9 | 206 |
| #11 | from 10 keep 1-8,12,15,17-19,25,28-30,33-36,39-40,42-43,45-47,52,54-56,58-59,63-66,68-69,71-74,76-77,79,81,83-85,87,89,91-92,94-95,98-99,101,105,107-108,110,114-118,124-126,128,134,137-138,140,143,146,148-150,154-155,157-163,165-174,176-177,179-181,183-186,188-190,192-203,206 | 126 |
| Topic | Knee | |
| #1 | knee\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 9.647 |
| #2 | brace\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 744 |
| #3 | knee-ankle-foot orthos\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 53 |
| #4 | ankle\$.mp. [mp=title, subject heading word, abstract, instrumentation] | 4.873 |
| #5 | 3 or 4 | 4.873 |
| #6 | 1 and 2 | 197 |
| #7 | 6 not 5 | 156 |
| #8 | from 7 keep 1,3-10,12-14,16-21,23-26,28-30,32-40,45-46,48,50-52,54-56,58-67,71-74,76-77,80-87,89,92-95,97-102,104,106-109,114-120,123-130,133-137,139-142,144-145,147-151,153-156 | 118 |

Table 8: BNI searches <1985 to January 2007>

| Queries | Search terms | Results |
|--------------|-------------------------------|---------|
| Topic | Cervical | |
| #1 | cervic\$.mp. [mp=ti, ab, hw] | 692 |
| #2 | collar\$.mp. [mp=ti, ab, hw] | 25 |
| #3 | splint\$.mp. [mp=ti, ab, hw] | 29 |
| #4 | 2 or 3 | 54 |
| #5 | 1 and 4 | 4 |
| #7 | systematic review.mp. | 601 |
| #8 | 6 or 7 | 605 |
| #9 | 5 and 8 | 4 |
| #10 | from 9 keep 2-3 | 2 |
| Topic | Wrist | |
| #1 | wrist\$.mp. [mp=ti, ab, hw] | 44 |
| #2 | splint\$.mp. [mp=ti, ab, hw] | 29 |
| #3 | brace\$.mp. [mp=ti, ab, hw] | 16 |
| #4 | bracing\$.mp. [mp=ti, ab, hw] | 4 |
| #5 | 2 or 3 or 4 | 47 |
| #6 | 1 and 5 | 1 |
| #7 | from 6 keep 1 | 1 |
| Topic | Knee | |
| #1 | 1 knee\$.mp. [mp=ti, ab, hw] | 188 |
| #2 | 2 brace\$.mp. [mp=ti, ab, hw] | 16 |
| #6 | 6 1 and 2 (0) | 0 |
| #8 | 8 from 2 keep 6 (1) | 1 |

Table 9: Embase searches

| Queries | Search terms | Results |
|--------------|--|---------|
| Topic | Cervical | |
| #1 | cervic* | 141.810 |
| #2 | splint* | 12.595 |
| #3 | collar* | 7.452 |
| #4 | brace* | 7.127 |
| #5 | bracing* | 1.626 |
| #6 | 2 OR 3 OR 4 OR 5 | 27.403 |
| #7 | 1 AND 6 | 1.197 |
| #8 | 1 AND 6 AND ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND ([dutch]/lim OR [english]/lim OR [french]/lim OR [german]/lim) AND [humans]/lim AND [embase]/lim | 30 |
| #9 | Records downloaded | 15 |
| Topic | Wrist | |
| #1 | 'wrist'/exp/mj OR 'wrist' | 23.068 |
| #2 | splint* | 12.595 |
| #3 | brace* | 7.127 |
| #4 | bracing* | 1.626 |
| #5 | 2 or 3 or 4 | 20.114 |
| #6 | 1 and 5 | 835 |
| #7 | 1 AND 5 AND ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND ([dutch]/lim OR [english]/lim OR [french]/lim OR [german]/lim) AND [humans]/lim AND [embase]/lim | 31 |
| #8 | Records downloaded | 20 |
| Topic | Knee | |
| #1 | knee* | 84.495 |
| #2 | brace* | 7.127 |
| #3 | bracing* | 1.626 |
| #4 | 2 OR 3 | 7.778 |
| #5 | 1 AND 4 | 1.214 |
| #6 | 1 AND 4 AND ([cochrane review]/lim OR [controlled clinical trial]/lim OR [meta analysis]/lim OR [randomized controlled trial]/lim OR [systematic review]/lim) AND ([dutch]/lim OR [english]/lim OR [french]/lim OR [german]/lim) AND [humans]/lim AND [embase]/lim | 56 |
| #7 | systematic review.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (8420) | 8.420 |
| #8 | Records downloaded | 29 |

Table 10: PEDro searches

| Queries | Search terms | |
|---------|---|---------|
| Topic | Cervical | Results |
| #1 | Therapy field: orthoses, taping, splinting Method: practice guideline, systematic review or clinical trial Body part field: head and neck | 86 |
| #2 | Articles selected | 38 |
| Topic | Wrist | |
| #1 | Therapy field: orthoses, taping, splinting Method: practice guideline, systematic review or clinical trial Body part field: hand or wrist | 118 |
| #2 | Articles selected | 58 |
| Topic | Knee | |
| #1 | Therapy field: orthoses, taping, splinting Method: practice guideline, systematic review or clinical trial Body part field: lower leg or knee | 195 |
| #2 | Articles selected | 51 |

Table 11: CIRRIE searches

| Queries | Search terms | |
|---------|--|---------|
| Topic | Cervical | Results |
| #1 | < collar > as title keyword and <Orthotics> as subject heading | 4 |
| Topic | Wrist | |
| #1 | <wrist> as title keyword and <Orthotics> as subject heading | 2 |
| Topic | Knee | |
| #1 | <knee> as title keyword and <Orthotics> as subject heading | 14 |
| #2 | Articles selected | 3 |

Table 12: REHABDATA searches

| Queries | Search terms | |
|---------|---------------------|---------|
| Topic | Cervical | Results |
| #1 | < cervical collar > | 7 |
| #2 | Articles selected | 6 |
| Topic | Wrist | |
| #1 | <wrist brace> | 2 |
| Topic | Knee | |
| #1 | <knee brace> | 26 |
| #2 | Articles selected | 20 |

APPENDIX TO CHAPTER III

English questionnaire

INSTITUTIONAL SETTING OF THE ORTHOPEDIC DEVICE MARKET:

Questionnaire

Instructions: Please respond to questions electronically. You can move forward through the main body of the questionnaire by pressing "Tab" and backwards by pressing "Shift + Tab", or you can use the scroll feature and the mouse. Boxes can be ticked and ticks can be removed by double-clicking the mouse.

IDENTIFICATION

| | |
|---------------|--|
| Country Name: | |
|---------------|--|

Contact Details for the Person Completing the Form

| | |
|--------------|--|
| Name: | |
| Title: | |
| Institution: | |
| Address: | |
| Country: | |
| Telephone: | |
| Fax: | |
| Email: | |

Correspondence address:

Steven Simoens

Research Centre for Pharmaceutical Care and Pharmaco-economics

Faculty of Pharmaceutical Sciences

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Onderwijs en Navorsing 2, P.O. Box 521

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3000 Leuven

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The market for orthotic devices is extensive and covers multiple types of devices. This questionnaire deals with the specific regulation applicable to prefabricated cervical braces, wrist braces and knee braces only. If there is no specific regulation regarding prefabricated cervical, wrist and knee braces, please refer to the general regulation governing orthotic devices that applies to these three types of braces.

This part of the questionnaire deals with the use of prefabricated cervical braces, wrist braces and knee braces in ambulatory care in your country.

| Section I. Pricing of cervical, wrist and knee braces | | |
|--|--|--|
| I.1 | Describe the mechanism by which prices of cervical, wrist and knee braces are set: | |
| .a | Free market pricing: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe system of free market pricing: | |
| .b | Fixed pricing: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe system of price fixing: | |
| .c | Other (please specify): | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| I.2 | Describe the principal bodies or agencies that are involved in pricing of cervical, wrist and knee braces: | |
| I.3 | Is there a procedure for revising prices of cervical, wrist and knee braces on national/regional lists? <i>If "No", go to question I.4</i> | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .a | If "Yes", describe which factors are taken into account when revising prices (e.g. change in production costs, evolution of price index): | |
| .b | Indicate how often prices are revised: | |
| I.4 | Any additional comments on pricing system of cervical, wrist and knee braces: | |

| Section 2. Reimbursement of cervical, wrist and knee braces | | |
|---|---|---|
| 2.1 | Describe the mechanism by which reimbursement of cervical, wrist and knee braces is set: | |
| .a | Public procurement at national level: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe system of tendering: | |
| .b | Public procurement at regional/local level: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe system of tendering: | |
| .c | National list of tariffs: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", specify how tariffs are set: | |
| | Also, specify name of national list: | |
| .d | Regional list of tariffs: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", specify how tariffs are set: | |
| | Also, specify name of regional list: | |
| .e | Other (please specify): | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| 2.2 | Which third-party payer reimburses cervical, wrist and knee braces? (<i>tick appropriate box</i>) | |
| .a | | National Health Service <input type="checkbox"/> Social insurance <input type="checkbox"/> |
| .b | Describe the process and decision criteria that are used for admitting a new brace to the system of third-party payer reimbursement: | |
| .c | Describe the process and decision criteria that are used for determining the level of third-party payer reimbursement of a new brace: | |
| .d | Are there any restrictions on reimbursement of cervical, wrist and knee braces (e.g. maximum number per month)? | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe restrictions: | |
| .e | Specify the level of patient co-payments for cervical, wrist and knee braces in ambulatory setting: | |
| 2.3 | Any additional comments on reimbursement system of cervical, wrist and knee braces: | |

| Section 3. Delivery channels | | |
|------------------------------|---|--|
| 3.1 | Describe principal bodies or agencies that distribute cervical, wrist and knee braces to patients: | |
| .a | Community pharmacies: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .b | Medical equipment shops: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .c | Orthopedists: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .d | Health authorities: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .e | Other (please specify): | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| 3.2 | Describe remuneration system for each type of distributor: | |
| .a | Community pharmacies: | |
| .b | Medical equipment shops: | |
| .c | Orthopedists: | |
| .d | Health authorities: | |
| .e | Other (please specify): | |
| 3.3 | Specify market share of each type of distributor (and give reference of publication if available): | |
| .a | Community pharmacies: | |
| .b | Medical equipment shops: | |
| .c | Orthopedist: | |
| .d | Health authorities: | |
| .e | Other (please specify): | |
| 3.4 | Does the distributor need to maintain or repair cervical, wrist and knee braces? <i>If "No", go to question 3.5</i> | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .a | If "Yes", describe the length of time during which the brace benefits from a guarantee: | |
| .b | Describe how the distributor is remunerated for providing a guarantee: | |
| 3.5 | Any additional comments on delivery channels: | |

| Section 4. Prescribing process | | |
|--------------------------------|---|---|
| 4.1 | Which party issues the first prescription? (tick appropriate box) | Specialist physician <input type="checkbox"/> Nurse practitioner <input type="checkbox"/> General practitioner <input type="checkbox"/> |
| .a | | |
| .b | Prescriptions generally refer to cervical, wrist and knee braces by: (tick appropriate box) | Generic name (type of device) <input type="checkbox"/> Specific brand name <input type="checkbox"/> |
| .c | Does the prescription need to be renewed after a certain amount of time? If "No", go to question 4.2 | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", which party renews prescriptions for cervical, wrist and knee braces? (tick appropriate box) | Specialist physician <input type="checkbox"/> Nurse practitioner <input type="checkbox"/> General practitioner <input type="checkbox"/> Orthopedist <input type="checkbox"/> |
| | How much time needs to expire before a prescription can be renewed? | |
| 4.2 | Are patients allowed to switch from the prescribed brace to another brace if the prescribed brace does not fit? If "No", go to question 4.3 | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| .a | If "Yes", describe regulation governing switches: | |
| .b | Who pays the additional amount if the patient switches to a brace with a higher reimbursement level (tick appropriate box) | National Health Service <input type="checkbox"/> Social insurance <input type="checkbox"/> Patient <input type="checkbox"/> |
| 4.3 | Any additional comments on prescribing process: | |

The remainder of the questionnaire deals with the use of prefabricated cervical braces, wrist braces and knee braces in the hospital setting in your country.

| Section 5. Hospital setting | | |
|-----------------------------|---|---|
| 5.1 | Which party pays for cervical, wrist and knee braces in hospital? (tick appropriate box) | Hospital <input type="checkbox"/> Patient <input type="checkbox"/> |
| .a | | |
| .b | Specify the level of patient co-payments for cervical, wrist and knee braces in hospital: | |
| .c | Are there any restrictions on reimbursement of cervical, wrist and knee braces in hospital (e.g. maximum number per month)? | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |
| | If "Yes", describe restrictions: | |
| 5.2 | Any additional comments on provision of cervical, wrist and knee braces in hospital?: | |

thank you for your assistance

Please return questionnaire by e-mail to:

steven.simoens@pharm.kuleuven.be

French questionnaire

CADRE INSTITUTIONNEL DU MARCHÉ POUR LE MATÉRIEL ORTHOPÉDIQUE :

Questionnaire

Instructions: Veuillez répondre aux questions dans un format électronique. Vous pouvez parcourir le document en tapant « Tab » et revenir en arrière en tapant « Shift + Tab », ou vous pouvez utiliser la roulette de votre souris. Les cases peuvent être cochées et décochées par un double-clic gauche de la souris.

IDENTIFICATION

| | |
|-----------------|--|
| NOM du Pays: | |
|-----------------|--|

Coordonnées de la personne complétant le document

| | |
|-------------------|--|
| Nom: | |
| Fonction: | |
| Organisation: | |
| Adresse: | |
| Pays: | |
| Numéro de Tel: | |
| Fax: | |
| Email: | |

adresse de retour:

Steven Simoens

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Le marché pour le matériel orthopédique est exhaustif et il couvre différents types de matériel. Ce questionnaire concerne la réglementation spécifique applicable uniquement aux orthèses préfabriquées : les orthèses du cou, les orthèses du poignet et les orthèses du genou. S'il n'y pas de réglementation spécifique concernant les orthèses préfabriquées du cou, du poignet ou du genou, nous vous prions de vous référer à la réglementation générale concernant le matériel orthopédique qui s'applique à ces 3 types d'orthèses.

La partie de ce questionnaire a trait à l'utilisation des orthèses préfabriquées du cou, du poignet et du genou dans le domaine des soins ambulatoires dans votre pays (en l'occurrence en France).

| Section I. Prix des orthèses du cou, du poignet et du genou | | |
|--|--|---|
| 1.1 | Décrivez la façon dont sont établis les prix des orthèses du cou, du poignet et du genou : | |
| .a | Système libre de fixation des prix du marché: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "Oui", décrivez le système libre de fixation des prix: | |
| .b | Système « fixe » de fixation des prix : | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "Oui", décrivez le système fixe de fixation des prix | |
| .c | Autres (veuillez spécifier): | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| 1.2 | Décrivez les organismes principaux ou les agences impliquées dans l'établissement des prix des orthèses du cou, du poignet et du genou : | |
| 1.3 | Existe-t-il une procédure pour revoir les prix des orthèses du cou, du poignet et du genou dans des listes nationales/régionales ? Si "NON", allez à la question 1.4 | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .a | Si "oui", décrivez les facteurs pris en compte lors des révisions des prix (p.e. changements dans les coûts de production, évaluation des indices de prix,...) | |
| .b | Indiquez la fréquence des changements de prix : | |
| 1.4 | Commentaires supplémentaires sur le système de prix des orthèses du cou, du poignet et du genou : | |

| Section 2. Remboursement des orthèses du cou, du poignet et du genou | | |
|--|--|---|
| 2.1 | Décrivez le mécanismes de remboursement des orthèses du cou, du poignet et du genou: | |
| .a | Offre publique au niveau national : | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "oui", décrivez le système d'offre: | |
| .b | Offre publique au niveau regional/local: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "OUI", décrivez le système d'offre: | |
| .c | Liste nationale des tarifs: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "Oui", spécifiez la façon dont les tarifs sont établis: | |
| | Spécifiez également le nom de la liste nationale: | |
| .d | Liste régionale des tarifs: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "oui", spécifiez la façon dont les tarifs sont établis : | |
| | Spécifiez également le nom de la liste régionale : | |
| .e | Autres (veuillez spécifier) | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| 2.2 | Quel organisme tiers-payant rembourse les orthèses du cou, du poignet et du genou (cochez la case appropriée) | |
| .a | | Service National de Santé <input type="checkbox"/> Sécurité Sociale <input type="checkbox"/> |
| .b | Décrivez le processus et les critères de décision qui sont utilisés pour l'introduction d'une nouvelle orthèse dans le système de remboursement tiers-payant : | |
| .c | Décrivez le processus et les critères de décision qui sont utilisés pour déterminer le niveau de remboursement « tiers-payant » pour une nouvelle orthèse. | |
| .d | Existen-t-il des restrictions de remboursement pour les orthèses du cou, du poignet et du genou (par exemple, un nombre maximum par mois) ? | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "Oui", décrivez les restrictions: | |
| .e | Spécifiez le niveau de participation individuelle du payant (ticket modérateur) pour les orthèses du cou, du poignet et du genou pour un patient ambulatoire. | |
| 2.3 | Commentaires supplémentaires sur le système de remboursement des orthèses du cou, du poignet et du genou | |

| Section 3. Circuits de distribution | | |
|-------------------------------------|--|---|
| 3.1 | Décrivez les organismes principaux ou les agences qui distribuent les orthèses du cou, du poignet et du genou aux patients: | |
| .a | Pharmacies locales: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .b | Magasins de materiel médical | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .c | Orthopédistes-orthésistes: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .d | Organismes publics de santé: | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .e | Autres (veuillez préciser) | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| 3.2 | Décrivez le système de rémunération pour chaque type de distributeur: | |
| .a | Pharmacies locales: | |
| .b | Magasins de materiel médical | |
| .c | Orthopédistes-orthésistes: | |
| .d | Organismes publics de santé: | |
| .e | Autres (veuillez préciser) | |
| 3.3 | Spécifiez les parts de marché de chaque type de distributeur (et donner les références des publications si nécessaire) : | |
| .a | Pharmacies locales: | |
| .b | Magasins de materiel médical | |
| .c | Orthopédistes-orthésistes: | |
| .d | Organismes publics de santé: | |
| .e | Autres (veuillez préciser) | |
| 3.4 | Le distributeur, doit-il entretenir ou réparer les orthèses du cou, du genou ou du poignet? Si "NON", passer à la question 3.5 | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .a | Si "OUI", décrivez la durée pendant laquelle l'orthèse bénéficie d'une garantie : | |
| .b | Décrivez comment le distributeur est rémunéré pour fournir la garantie. | |
| 3.5 | Commentaires supplémentaires sur les circuits de distribution: | |

| Section 4. Procédures de prescription | | |
|--|---|--|
| 4.1 | Quelle personne ordonne la première prescription? (cochez la case appropriée) | Médecin spécialiste <input type="checkbox"/> Infirmière clinique <input type="checkbox"/> Médecin généraliste <input type="checkbox"/> |
| .a | En général, des références dans la prescription des orthèses du cou, du poignet et du genou concernent: (cochez la case appropriée) | Dénomination générique (type de matériel) <input type="checkbox"/> Dénomination spécifique du produit <input type="checkbox"/> |
| .c | La prescription doit-elle être renouvelée après un certain temps? | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .d | Quelle personne renouvelle les prescriptions pour les orthèses du cou, du poignet et du genou (cochez la case appropriée) | Médecin spécialiste <input type="checkbox"/> Infirmière clinique <input type="checkbox"/> Médecin généraliste <input type="checkbox"/> Orthopédiste-orthésiste <input type="checkbox"/> |
| .e | Combien de temps est-il nécessaire (du point de vue réglementaire) avant qu'une prescription ne soit renouvelée ?? | |
| 4.2 | Les patients ont-ils le droit de passer d'une orthèse prescrite à une autre orthèse si le matériel original ne convient pas ? Si "NON", aller à la question 4.3 | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| .a | Si "OUI", décrivez la procédure pour changer d'orthèse : | |
| .b | Qui paye le montant supplémentaire lorsque le patient passe à une orthèse avec un montant de remboursement plus élevé (cochez la case appropriée) | Service National de Santé <input type="checkbox"/> Sécurité Sociale <input type="checkbox"/> Patient <input type="checkbox"/> |
| 4.3 | Commentaires supplémentaires sur les procédures de prescription : | |

Le reste de ce questionnaire traite de l'utilisation des orthèses du cou, du poignet et du genou dans une institution hospitalière dans votre pays.

| Section 5. Institution hospitalière | | |
|--|---|--|
| 5.1 | Quelle instance paye pour les orthèses du cou, du poignet et du genou dans votre hôpital (cochez la case appropriée) | Hôpital <input type="checkbox"/> Patient <input type="checkbox"/> |
| .a | Spécifiez le niveau de paiement à charge du patient (ticket modérateur, suppléments) pour les orthèses du cou, du poignet et du genou dans l'hôpital | |
| .c | Existent-t-il des restrictions sur le remboursement des orthèses du cou, du poignet et du genou dans l'hôpital (par exemple, nombre maximum par mois) ? | OUI: <input type="checkbox"/> NON: <input type="checkbox"/> |
| | Si "OUI", décrivez les restrictions: | |
| 5.2 | Commentaires supplémentaires sur l'utilisation d'orthèses du cou, du poignet et du genou dans l'hôpital | |

Merci pour votre collaboration

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APPENDIX TO CHAPTER IV

Scope of selected billing codes (RIZIV/INAMI billing codes)

| Type of Device | RIZIVcode | Label_NL | Libellé_FR |
|----------------|-----------|---|---|
| NECK | 645175 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Soepele halskraag | Sont considérés comme relevant de la compétence des orthopédistes (T) - Tête - Cou - Tronc - Groupe principal II : Cou - Prefab - A l'avant : de la clavicule à la mandibule inférieure ; A l'arrière : de C 5 à la protubérance occipitale ; Sur le côté : sous les oreilles jusqu'aux épaules : Collier souple |
| | 645212 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Hoofd - Hals - Romp - Hoofdgroep II : Hals - Prefab - Vooraan : van claviculae tot onderkant mandibulae ; Achteraan : van C 5 tot protuberantia occipitalis ; Opzij : onder de oren tot op de schouders : Stijve halskraag met kin- en/of achterhoofdsteun, regelbaar in de hoogte | Sont considérés comme relevant de la compétence des orthopédistes (T) - Tête - Cou - Tronc - Groupe principal II : Cou - Prefab - A l'avant : de la clavicule à la mandibule inférieure ; A l'arrière : de C 5 à la protubérance occipitale ; Sur le côté : sous les oreilles jusqu'aux épaules : Collier rigide avec appui-menton et/ou occiput, réglable en hauteur |
| KNEE | 647533 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab : Kniestuk uit stof of elastisch weefsel of neopreen met metalen versterking, geleed aan de knie, geprefabriceerd model met individuele aanpassing | Sont considérés comme relevant de la compétence des orthopédistes (T) - Membres inférieurs - Groupe principal III : Genou : Genouillère en tissu ou tissu élastique ou en néoprène avec renfort métallique, articulé au genou, modèle préfabriqué à adaptation individuelle |
| | 647555 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab : Kniestuk, soepel geweven, al dan niet met neopreen, versterkt met baleinen | Sont considérés comme relevant de la compétence des orthopédistes (T) - Membres inférieurs - Groupe principal III : Genou : Genouillère, en tissu souple, en néoprène ou non, renforcée de baleines |
| | 647592 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Onderste ledematen - Hoofdgroep III : Knie - Prefab - Distal : helft onderbeen ; Proximaal : helft bovenbeen - De dij wordt gemeten aan de mediale zijde van het been, van de kniespleet tot de ramus ossis pubis : Knieapparaat, stevig, met vaste structuur dat de volledige omtrek van de dij en kuit omvat, met kniescharnier, al dan niet regelbaar | Sont considérés comme relevant de la compétence des orthopédistes (T) - Membres inférieurs - Groupe principal III : Genou - Distal : mi-jambe ; Proximal : mi-cuisse. La cuisse est mesurée à la face interne de la jambe, de la fente du genou jusqu'au rameau de l'os pubien : Appareil de genou robuste, avec structure fixe prenant toute la circonférence de la cuisse et du mollet, à charnières, réglable ou non |
| WRIST | 649434 | Worden geacht in de bevoegdheid van de orthopedisten (T) te vallen - Bovenste ledematen - Hoofdgroep IV : Pols - Van midden metacarpaal tot 1/3 proximaal van het polsgewricht - Prefab : Sterk bewegingsbeperkende polsbandage met harde verstijving | Sont considérés comme relevant de la compétence des orthopédistes (T) - Membres supérieurs - Groupe principal IV : Poignet - Du milieu du métacarpe à 1/3 proximal de l'articulation du poignet - Préfab : Bandage du poignet fortement restricteur de mouvement avec renforcement dur |

EUROPEAN MEDICAL DEVICE MARKET

| European medical device markets ranked by size, 2002 | | | |
|--|--------------------|--------------------|--------------------------|
| | Expenditure (€mil) | Population | Expenditure / capita (€) |
| Germany | 19.000 | 82.689.210 | 230 |
| Norway | 930 | 4.620.275 | 201 |
| Switzerland | 1.360 | 7.252.331 | 188 |
| Denmark | 870 | 5.430.590 | 160 |
| Netherlands | 2.500 | 16.299.170 | 153 |
| France | 9.000 | 60.495.540 | 149 |
| Sweden | 1.000 | 9.041.262 | 111 |
| Luxemburg | 50 | 464.904 | 108 |
| Italy | 6.160 | 58.092.740 | 106 |
| United Kingdom | 5.800 | 59.667.840 | 97 |
| Austria | 730 | 8.189.444 | 89 |
| Ireland | 360 | 4.147.901 | 87 |
| Finland | 450 | 5.249.060 | 86 |
| Belgium | 820 | 10.419.050 | 79 |
| Spain | 3.000 | 43.064.190 | 70 |
| Portugal | 600 | 10.494.500 | 57 |
| Greece | 540 | 11.119.890 | 49 |
| Total | 53.170 | 396.737.897 | 134 |

Source: Eucomed (2004), most but not all figures refer to year 2002. Population data http://en.wikipedia.org/wiki/list_of_countries_by_population_density (source mentioned United Nations World Population Prospects (2004 revision) data is for 2005

Growth (%) of sub-markets in Europe

| Growth (%) of selected sub-markets in europe | | | | | |
|--|----------|----------|-----------|-----------|-------------|
| | 1999 | 2000 | 2001 | 2002 | 2003 |
| Computer tomography | n.a. | 18 | 41 | 18 | 3 |
| Magnetic resonance | n.a. | 4 | 36 | 15 | -4 |
| Ultrasound | n.a. | 15 | 19 | 13 | 12 |
| X ray | n.a. | 21 | -9 | 9 | -13 |
| Radiology information systems (RIS) and picture archiving and communication systems (PACS) | n.a. | n.a. | n.a. | 25 | 15 |
| In vitro diagnostics | 3,8 | 4,6 | 7,3 | 6 | 5,6 |
| Orthopaedics | 7 | 9 | 12 | 16 | n.a. |
| Dental | n.a. | 17 | -6 | 12 | -10 |

Source: COCIR (for computer tomography, magnetic resonance, ultrasound, x ray, RIS & PACS), EDMA (2004; for in vitro diagnostics); ADDE & FIDE (2004; for dental), on estimates based on Datamonitor (2003b) and discussion with the industry (for orthopaedics)

SURVEY TO THE ORTHOTISTS¹

Scope of the products of the survey²

- The knee orthoses:
 - Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)
 - Prefab knee bandage woven reinforced (nomenclature code 647555)
 - Prefab hard knee brace hinged (nomenclature code 647592)
 - Prefab hard knee brace with adjustable hinge (nomenclature code 647614)
 - Prefab knee brace woven with firm structure (nomenclature code 655690)
- The neck orthoses:
 - Prefab soft collar (nomenclature code 645175)
 - Prefab stiff neck collar adjustable in height or not (nomenclature code 645190)
 - Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)
 - Prefab Halo brace (nomenclature code 645293)
- The wrist orthose:
 - Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

Methodology of the survey

The survey was distributed to the orthopaedics by the BBOB-UPBOB and the responses were collected by them.

The survey asked for information on the specific brands and types of the three most frequently delivered products for each nomenclature code, their percentage of total sales, the product brand name and information on the provider of the product.

The BBOB-UPBOB converted the responses into one list of products classified according to the nomenclature codes of the RIZIV / INAMI used for reimbursement. The list provided by the BBOB-UPBOB did however not mention the relative importance of the different products listed. The list was communicated to the KCE and is added to this appendix.

¹ The survey was organised before the project expert committee on the 26th of January 2007 approved the final selection of the nomenclature codes to be used for the market analysis. This explains why more nomenclature codes were used in this survey than the codes of the final selection

² Own translation KCE

Questionnaire survey to the orthotists

| Category | % Patients | Code | Main medical indications | Main products on the market (3 products per Code) + Cheapest Product on the Market (1 product) If Cheapest Product is among the most frequently sold, repeat product description at line 4) | | | | | |
|-------------|------------|--------|--------------------------|---|----------------|-------------------------|-----------------------|--|--|
| | | | | Product Identity: Name, Reference | %sold products | Product Brand Name | Product Producer Name | | |
| Knie- Genou | | 647592 | | <i>Main Product</i> | | | | | |
| | | | | <i>Product Nr.2</i> | | | | | |
| | | | | <i>Product Nr.3</i> | | | | | |
| | | | | <i>Cheapest product</i> | | | | | |
| | | 647555 | | 647555 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| | | 647533 | | 647533 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| | | 647614 | | 647614 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| | | 655690 | | 655690 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |

| Category | % Patients | Code | Main medical indications | Main products on the market (3 products per Code) + Cheapest Product on the Market (1 product) If Cheapest Product is among the most frequently sold, repeat product description at line 4) | | | | | |
|--------------|------------|--------|--------------------------|---|----------------|-------------------------|-----------------------|--|--|
| | | | | Product Identity: Name, Reference | %sold products | Product Brand Name | Product Producer Name | | |
| Hals-Cou | | 645293 | | <i>Main Product</i> | | | | | |
| | | | | <i>Product Nr.2</i> | | | | | |
| | | | | <i>Product Nr.3</i> | | | | | |
| | | | | <i>Cheapest product</i> | | | | | |
| | | 645175 | | 645175 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| | | 645212 | | 645212 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| | | 645190 | | 645190 | | <i>Main Product</i> | | | |
| | | | | | | <i>Product Nr.2</i> | | | |
| | | | | | | <i>Product Nr.3</i> | | | |
| | | | | | | <i>Cheapest product</i> | | | |
| Pols-Poignet | | 649434 | | <i>Main Product</i> | | | | | |
| | | | | <i>Product Nr.2</i> | | | | | |
| | | | | <i>Product Nr.3</i> | | | | | |
| | | | | <i>Cheapest product</i> | | | | | |

Answers Survey to the Orthotists

List of distributors used by the orthotists

- Axamed
- Bauerfeind Benelux
- Dirame
- Distrac
- Medi Belgium
- Ortho-Medico
- Ortimex
- Ossur Europe
- Otto Bock Benelux
- Somas Orthopedie
- Sprofit
- Thuasne
- Vitamed

Products sold by the Orthotists (answers to the survey)

| Artikel | leverancier |
|---|-------------------------|
| Halo brace 645293 | |
| <i>Lerman non-invasive Halo</i> | Ortimex |
| <i>Lerman pediatric Halo</i> | Ortimex |
| <i>Halo brace complete system</i> | Ortimex |
| <i>PMT</i> | Somas Orthopaedie |
| <i>PMT pediatric</i> | Somas Orthopaedie |
| <i>Complete Halo System/Jerome</i> | Ortho-Medico |
| <i>Mediplant</i> | Johnson-Johnson Medical |
| Soepele halskraag (All1) 645175 | |
| <i>Scott cervical collar</i> | Ortimex |
| <i>Globus 008, 108,110,210</i> | Globus |
| <i>Globus 101,102</i> | Globus |
| <i>Globus 112</i> | Globus |
| <i>Globus 212</i> | Globus |
| <i>Thämert 49/190</i> | Axamed |
| <i>Push nek Care 8 cm en 10 cm</i> | vitamed |
| <i>Push nek Med 8 cm en 10 cm</i> | vitamed |
| <i>Camp 5750, 5700, 5800</i> | Dirame |
| <i>Camp 5620/21, 5720/21, 5820/21</i> | Dirame |
| <i>Ormihl C114-7-1/2/3, C119-9-1/2/3</i> | Dirame |
| <i>Collier cervical Tricodur</i> | Jobst |
| <i>Necky Color micro 8/10/12 réf. 103C/104C /105C</i> | Otto Bock |
| <i>Cervilastic</i> | Somas Orthopaedie |
| <i>Cervicadyn</i> | Somas Orthopaedie |
| <i>Cervi-hit</i> | Somas Orthopaedie |
| <i>medi Active Strong</i> | medi |
| <i>Bort Stabilo 127160</i> | Axamed |
| <i>Bort Cervical Support 127260</i> | Axamed |
| <i>Bort Cervical Support 127360</i> | Axamed |
| <i>Bort Stabilonec 127560</i> | Axamed |
| <i>DeRoyal zachte halskraag 6/8/10/12 ref EU 515</i> | Ortho-Medico |

| Stijve halskraag regelbaar in de hoogte 645212 | |
|---|-------------------|
| <i>Jerome Necloc acute care collar- ref 95</i> | Ortho-Medico |
| <i>Jerome Miami J - ref 90</i> | Ortho-Medico |
| <i>Exo-static halskraag met kinsteun ref 1001403</i> | Ortimex |
| <i>Ortimex Adjustable ortho-collar ref 105320</i> | Ortimex |
| <i>Marlin cervical orthoses</i> | Ortimex |
| <i>Distrac malibu halskraag 06/3020</i> | Distrac |
| <i>Camp 5900</i> | Dirame |
| <i>Fillauer Ortho Collar</i> | Dirame |
| <i>Exo-collar</i> | Dirame |
| <i>Ormihl Kleb'air collar</i> | Dirame |
| <i>DDS Cervicale tractie collar</i> | Dirame |
| Stijve halskraag al dan niet regelbaar 645190 | |
| <i>Ortimex Exo-static halskraag ref 1001303</i> | Ortimex |
| <i>Ortimex Form fit cervical collar ref 83043</i> | Ortimex |
| <i>Camp simple+ régl en hauteur réf 5600</i> | Dirame |
| <i>Push med 8-10</i> | Vitamed |
| <i>Sporlastic Halskraag</i> | Somas Orthopaedie |
| <i>medi Exo Static Collar</i> | medi |
| <i>Bort cervical support 127060</i> | Axamed |
| <i>Phil collar</i> | Ortimex |
| <i>Cerviflex Strong</i> | Bauerfeind |
| <i>PHILADELPHIA COLLAR</i> | Distrac |
| <i>Alliance</i> | Dirame |

| Artikel | leverancier |
|---|-------------------|
| knieband type ACL 647592 | |
| <i>genu arexa</i> | Otto Bock Benelux |
| <i>Mos court</i> | Bauerfeind |
| <i>Défiance Donjoy</i> | Dirame |
| <i>Funct. brace Armor</i> | Dirame |
| <i>Funct. brace Defiance</i> | Dirame |
| <i>Funct. brace Force Point</i> | Dirame |
| <i>Funct. brace Legend</i> | Dirame |
| <i>Funct. brace Rebel</i> | Dirame |
| <i>Osteo arthr. brace OA Defiance</i> | Dirame |
| <i>Osteo arthr. brace Reliever</i> | Dirame |
| <i>Mos long</i> | Bauerfeind |
| <i>Secutec Genu</i> | Bauerfeind |
| <i>CTI</i> | Somas |
| <i>Lenox hill brace</i> | Thuasne |
| <i>GII PACK ou OA</i> | Ossur Europe |
| <i>Precision Pro ACL/PCL</i> | Ortimex |
| <i>Precision Fit</i> | Ortimex |
| <i>V3 Custom fit</i> | Ortimex |
| <i>Cruiser (medial/lateral) OTS & custom</i> | Ortimex |
| <i>Cti II (custom)</i> | Somas Orthopaedie |
| <i>Cti morph</i> | Somas Orthopaedie |
| <i>Cti flex</i> | Somas Orthopaedie |
| <i>Cti oasis</i> | Somas Orthopaedie |
| <i>Generation II extreme op maat</i> | Ossur Europe |
| <i>Generation II unloader express</i> | Ossur Europe |
| <i>Generation II unloader adj</i> | Ossur Europe |
| <i>Generation II polyaxial knee cage (PAKC)</i> | Ossur Europe |
| <i>3DX</i> | Ossur Europe |
| <i>Donjoy legend</i> | Sprofit |
| <i>Donjoy 4-titude</i> | Sprofit |
| <i>Donjoy armor moto/ski</i> | Sprofit |
| <i>Donjoy oadjuster</i> | Sprofit |
| <i>Donjoy fource point</i> | Sprofit |
| <i>Bledsoe Axiom Sport (nieuwe naam voor Knee Cage)</i> | Ortho Medico |
| <i>Bledsoe Ultimate Dynamic</i> | Ortho Medico |
| <i>Bledsoe Axiom</i> | Ortho Medico |
| <i>Bledsoe Axiom maatwerk</i> | Ortho Medico |
| <i>Bledsoe Aligner (medial - lateral)</i> | Ortho Medico |
| <i>Bledsoe Thruster (medial - lateral)</i> | Ortho Medico |
| <i>medi M.4 ACL</i> | medi |
| <i>medi M.4 PCL</i> | medi |
| <i>medi M.4 CI</i> | medi |
| <i>medi M.4 Vario</i> | medi |
| <i>medi M.4 OA</i> | medi |
| <i>protect. 4</i> | medi |
| <i>Bort OTS Knee Brace 100600</i> | Axamed |
| <i>PLUSPOINT Functional Kneebbrace</i> | Distrac |

| Artikel | leverancier |
|---|-------------------|
| knieband met baleinen 647555 | |
| <i>genu medi</i> | Medi |
| <i>push care</i> | Vitamed |
| <i>genutrain</i> | Bauerfeind |
| <i>elcross 121</i> | Dirame |
| <i>elcross 122</i> | Dirame |
| <i>genutrain P3</i> | Bauerfeind |
| <i>Genutrain A3</i> | Bauerfeind |
| <i>push med</i> | Vitamed |
| <i>genu immobil 0°</i> réf. 08060 | Otto Bock Benelux |
| <i>genu basic EQ</i> réf. 2033 | Otto Bock Benelux |
| <i>OM immob knee immobilizer - ref IMMOB</i> | Ortho Medico |
| <i>genu sensa</i> | Otto Bock Benelux |
| <i>Patella stabilizer Bioskin</i> | Somas Orthopaedie |
| <i>Gladiator</i> | Somas Orthopaedie |
| <i>medi elastic knee support 603</i> | medi |
| <i>medi elastic knee support 605</i> | medi |
| <i>protect.genu</i> | medi |
| <i>Bort Knee Bandage 114150</i> | Axamed |
| <i>Bort Knee Bandage 114250</i> | Axamed |
| <i>Bort Knee Bandage 114390</i> | Axamed |
| <i>Bort Knee Bandage 114420</i> | Axamed |
| <i>Bort Knee Bandage 114430</i> | Axamed |
| <i>Bort Knee Bandage 114450</i> | Axamed |
| <i>Bort Knee Bandage 114490</i> | Axamed |
| <i>Bort Knee Bandage 114520</i> | Axamed |
| <i>Bort Knee Bandage 114700</i> | Axamed |
| <i>DeRoyal Knee brace with flexible stays ref 8052</i> | Ortho Medico |
| <i>DeRoyal Genum Stabiliser Long Silicon beige(T3) - ref EU</i> | Ortho Medico |
| <i>DeRoyal Genum Stabiliser Long (T3) - ref EU 4131</i> | Ortho Medico |
| <i>OBJECT kniebandage M.808</i> | Distrac |
| <i>Air Donjoy 11-0663,</i> | Dirame |
| <i>Lateral J 11-0320, 0321, 0659, 0660</i> | Dirame |
| <i>H-butress 11-0032, 0322, 0323, 0432, 0324, 0325</i> | Dirame |
| <i>Deluxe donut 11-0327, 0328, 0380, 0381</i> | Dirame |
| <i>Horse Shoe 11-0334, 0342, 0344, 0343</i> | Dirame |

| Artikel | leverancier |
|--|-------------------|
| knieband met scharnieren 647533 | |
| <i>Hinged knee support</i> | Ortimex |
| <i>Wrap around knee support</i> | Ortimex |
| <i>Elcross</i> réf. 124,126, 128 en v | Dirame |
| <i>genu flex 8151</i> | Otto Bock Benelux |
| <i>genutrain S</i> | Bauerfeind |
| <i>Hinged Knee Economy</i> réf.11-0372 | Donjoy |
| <i>genu EQ combi stable</i> réf.2262 | Otto Bock Benelux |
| <i>Genu combi stable EQ</i> réf. 2262 | Otto Bock Benelux |
| <i>genu lock 8152</i> | Otto Bock Benelux |
| <i>genu combi basic 8153</i> | Otto Bock Benelux |
| <i>G2 trainer</i> | Össur |
| <i>genu stable 2259</i> | Otto Bock Benelux |
| <i>Short Runner</i> | Pabisch |
| <i>PTO (patellar tracking orthosis)</i> | Pabisch |
| <i>Bledsoe Sportmax - ref 3175</i> | Ortho Medico |
| <i>DeRoyal Genum Liga (T3) - ref EU 4112</i> | Ortho Medico |
| <i>DeRoyal Genum Liga ACL (T3) - ref EU 4110</i> | Ortho Medico |
| <i>Donjoy Tru-Pull hinged sleeve</i> | Sprofit |
| <i>Hinged Knee Bioskin</i> | Somas Orthopaedie |
| <i>Stabimed II Pro</i> | medi |
| <i>Airtex hinged knee pro</i> | medi |
| <i>Stabimed II</i> | medi |
| <i>Airtex hinged knee wrap</i> | medi |
| <i>protect.Co</i> | medi |
| <i>protect.St</i> | medi |
| <i>protect.St pro</i> | medi |
| <i>protect.OA soft</i> | medi |
| <i>Bort Knee Bandage 114460</i> | Axamed |
| <i>Bort Knee Bandage 114480</i> | Axamed |
| <i>Bort Stabilo 150140</i> | Axamed |
| <i>OBJECT Kniebandage M.815</i> | Distrac |
| <i>Economy hinged knee</i> | Dirame |
| <i>Drytex economy hinged knee 11-0671</i> | Dirame |
| <i>Opal</i> | Dirame |
| <i>Tru Pull hinged</i> | Dirame |

| Artikel | leverancier |
|---|-------------------|
| knieband post op 647614 | |
| <i>GII rehab</i> | Össur |
| <i>Knee ranger lite universal</i> | Ortimex |
| <i>Post-op knee brace cool</i> | Ortimex |
| <i>Post-op knee brace premium</i> | Ortimex |
| <i>Bledsoe Adjustable brace - ref 3010</i> | Ortho Medico |
| <i>Bledsoe O.R. brace - ref 3011 (long) en 3012 (regular)</i> | Ortho Medico |
| <i>Bledsoe Revolution - ref 3013</i> | Ortho Medico |
| <i>Bledsoe Extender</i> | Ortho Medico |
| <i>Post-op short, Breg 07590</i> | Pabisch |
| <i>Polaris orthome r ica</i> | Dirame Ortho |
| <i>Postop kniebrace GII rehab universal air light</i> | Ossur Europe |
| <i>Vector</i> | Somas Orthopaedie |
| <i>Option</i> | Somas Orthopaedie |
| <i>Quick Lock</i> | Somas Orthopaedie |
| <i>Sentry</i> | Somas Orthopaedie |
| <i>Collamed II</i> | medi |
| <i>medi ROM</i> | medi |
| <i>medi ROM Cool</i> | medi |
| <i>protect.ROM</i> | medi |
| <i>protect.ROM Cool</i> | medi |
| <i>Post-op Kniebrace met Regain Scharnieren 95500</i> | Distrac |
| <i>Playmaker</i> | Dirame |
| <i>Hinged knee</i> | Dirame |
| <i>Eco hinged knee</i> | Dirame |
| <i>Telescoping T-rom</i> | Dirame |
| <i>Fast fit T-Rom 0842</i> | Dirame |
| <i>Rehab T-rom 11-0295</i> | Dirame |
| <i>Telescoping Irom</i> | Dirame |
| <i>Telescoping Els</i> | Dirame |
| <i>CPB 11-0155, 0163,</i> | Dirame |
| <i>Competitor 11-0523</i> | Dirame |
| <i>Unitrac3 11-0937</i> | Dirame |
| <i>Rehab3 11-0927, 0928, 0929,</i> | Dirame |
| <i>Air Rehab 11-0924, 0925, 0926</i> | Dirame |
| <i>Universal laser lock Orthomerica</i> | Dirame |
| <i>Convertible TS</i> | Dirame |

| Artikel | leverancier |
|--|-------------|
| knieband met 3D breiwerk 655690 | |
| Softec Genu | Bauerfeind |
| <i>Niet in nomenclatuur, vraag om opname te overwegen</i> | |
| Ultraflex dynamic knee brace | dirame |

| Artikel | leverancier |
|--|-------------------|
| POLS 649434 | |
| Thumb-o-prene Donjoy | Sprofit |
| Confort doigt axmed | Axmed |
| Push med.splint pols | Vitamed |
| Elastic wrist brace Donjoy | Sprofit |
| Rolyan D-Ring wrist+thumb | Sprofit |
| ManuTrain | Bauerfeind |
| Cock-up wrist Bioskin | Somas Orthopaedie |
| Manu hit Sporlastic | Somas Orthopaedie |
| Sporlastic polsbandages | Somas Orthopaedie |
| Manumed | medi |
| medi wrist support | medi |
| protect.wrist uni | medi |
| Bort wrist support 103300 | Axamed |
| Bort wrist support 103301 | Axamed |
| Bort Sellatex 112050 | Axamed |
| Bort Manuzip 112220 | Axamed |
| Bort Manuzip 112320 | Axamed |
| Elastic wrist brace | Ortimex |
| DeRoyal - Manex Reuma Long - ref EU2024 | Ortho Medico |
| DeRoyal - Manex Reuma Pollus - ref EU 2025 | Ortho Medico |
| Ultimate Wrist Support | Distrac |
| Elcross 144, 141 | Dirame |
| Wrist laser | Dirame |
| Wrist rheno | Dirame |
| <i>Niet in nomenclatuur, vraag om opname te overwegen</i> | |
| Ultraflex dynamic wrist brace | dirame |

SURVEY TO THE DISTRIBUTORS

Types of products used for the survey

- The knee orthoses:
 - Prefab knee brace elastic tissue or neoprene reinforced with metal (nomenclature code 647533)
 - Prefab knee bandage woven reinforced (nomenclature code 647555)
 - Prefab hard knee brace hinged (nomenclature code 647592)
- The neck orthoses:
 - Prefab soft collar (nomenclature code 645175)
 - Prefab stiff neck collar with support chin and/or back of the head adjustable in height (nomenclature code 645212)
- The wrist orthose:

- Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

METHODOLOGY OF THE SURVEY

Distribution of the questionnaire was done by the BBOB-UPBOB and UNAMEC. Distributors were asked to provide information on the different products they distribute on the Belgian market. The products were ranked corresponding to the specific nomenclature codes of the RIZIV / INAMI nomenclature code. The type of products on which information was asked for corresponded to the type of products of the final scope of the study as determined by the Project expert committee.³

Most of the distributors acting on the Belgian market responded to the survey. The information that was provided to us by the BBOB-UPBOB and UNAMEC did however only mention the numbers of the respective products sold on the Belgian market, the selling prices (to the orthopaedics) and the brands. The buying prices and the cheapest products known were not mentioned.

Based on the answers to this survey and the additional information gathered, a list of products sold on the Belgian market (within the nomenclature codes of the scope) was drawn.

³ The detailed list of the types of orthoses are mentioned in annex 5 to the report

QUESTIONNAIRE USED IN THE SURVEY TO THE DISTRIBUTORS:

| Nomenclature code | Product | Distributor | Number of products sold / year | If no exact number TOP-10 most sold products | Purchase price from manufacturer | Selling price excl VAT | Your provider | Cheapest product known |
|-------------------|---|----------------|--------------------------------|--|----------------------------------|------------------------|---------------|------------------------|
| Knee | Bledsoe Aligner | Ortho-Medico | | | | | | |
| 647592 | Bledsoe Cage LR | Ortho-Medico | | | | | | |
| | Bledsoe Axiom Sport (new brand for Knee Cage) | Ortho Medico | | | | | | |
| | Bledsoe Ultimate Dynamic | Ortho Medico | | | | | | |
| | Bledsoe Axiom | Ortho Medico | | | | | | |
| | Bledsoe Axiom maatwerk | Ortho Medico | | | | | | |
| | Bledsoe Thruster (medial - lateral) | Ortho Medico | | | | | | |
| | SecuTec Genu LR | Bauerfeind BNL | | | | | | |
| | Breg Tradition OTS LR | W. Pabisch | | | | | | |
| | genu arexa | Otto Bock BNL | | | | | | |
| | MOS Genu long | Bauerfeind | | | | | | |
| | MOS Genu court | Bauerfeind | | | | | | |
| | Défiance Donjoy | Dirame | | | | | | |
| | Donjoy armor moto/ski | Dirame | | | | | | |
| | Donjoy Funct. brace Defiance | Dirame | | | | | | |
| | Donjoy OA Defiance | Dirame | | | | | | |
| | Funct. brace Force Point | Dirame | | | | | | |
| | Donjoy fource point | Sprofit | | | | | | |
| | Donjoy Legend Funct. brace ACL | Dirame | | | | | | |
| | Donjoy Legend Funct. brace | Sprofit | | | | | | |
| | Donjoy 4-titude | Sprofit | | | | | | |
| | Donjoy oadjuster | Sprofit | | | | | | |
| | Funct. brace Rebel | Dirame | | | | | | |
| | Osteo arthr. brace Reliever | Dirame | | | | | | |
| | THUASNE GENU PRO Control Clasic | Thuasne | | | | | | |
| | Precision Pro ACL/PCL | Ortimex | | | | | | |
| | Precision Fit | Ortimex | | | | | | |

| Nomenclature code | Product |
|-------------------|-------------------|
| | V3 Custom fit |
| | Cruiser (media |
| | CTI |
| | Cti II (custom) |
| | Cti morph |
| | Cti flex |
| | Cti oasys |
| | Generation II e |
| | Generation II u |
| | Generation II u |
| | Generation II p |
| | 3DX |
| | GII PACK ou C |
| | medi M.4 ACL |
| | medi M.4 PCL |
| | medi M.4 CI |
| | medi M.4 Vari |
| | medi M.4 OA |
| | protect.4 |
| | Bort OTS Kne |
| | PLUSPOINT F |
| | Knie Bregg Tr |
| | OTHER PROD |
| | |
| | |
| | |
| | |

| Nomenclature code | Product | Distributor | Number of products sold / year | If no exact number TOP-10 most sold products | Purchase price from manufacturer | Selling price excl VAT | Your provider | Cheapest product known |
|-------------------|---|---------------|--------------------------------|--|----------------------------------|------------------------|---------------|------------------------|
| Knee | Genutrain | Bauerfeind | | | | | | |
| 647555 | Genutrain P3 | Bauerfeind | | | | | | |
| | Genutrain A3 | Bauerfeind | | | | | | |
| | Genu Pro Actif | Bauerfeind | | | | | | |
| | Push Care | Vitamed | | | | | | |
| | Push Heavy | | | | | | | |
| | Push Med | Vitamed | | | | | | |
| | Push medium | | | | | | | |
| | Thuasne Silistab Genu | Thuasne | | | | | | |
| | elcross 121 | Dirame | | | | | | |
| | Basko Elcross 122 | Dirame | | | | | | |
| | Genu immobil 8060 | Otto Bock BNL | | | | | | |
| | Genu basic EQ | Otto Bock BNL | | | | | | |
| | Genu Sensa 50K15 | Otto Bock BNL | | | | | | |
| | Patella stabilizer Bioskin | Somas Orth | | | | | | |
| | Gladiator | Somas Orth | | | | | | |
| | Genu medi | Medi | | | | | | |
| | medi elastic knee support 603 | medi | | | | | | |
| | medi elastic knee support 605 | medi | | | | | | |
| | protect.genu | medi | | | | | | |
| | Bort Knee Bandage 114150 | Axamed | | | | | | |
| | Bort Knee Bandage 114250 | Axamed | | | | | | |
| | Bort Knee Bandage 114390 | Axamed | | | | | | |
| | Bort Knee Bandage 114420 | Axamed | | | | | | |
| | Bort Knee Bandage 114430 | Axamed | | | | | | |
| | Bort Knee Bandage 114450 | Axamed | | | | | | |
| | Bort Knee Bandage 114490 | Axamed | | | | | | |
| | Bort Knee Bandage 114520 | Axamed | | | | | | |
| | Bort Knee Bandage 114700 | Axamed | | | | | | |
| | OM Immob knee immobilizer - ref IMMOB | Ortho Medico | | | | | | |
| | DeRoyal Knee brace with flexible stays ref 8052 | Ortho Medico | | | | | | |
| | DeRoyal Genum Stabiliser Long Silicon beige | Ortho Medico | | | | | | |
| | DeRoyal Genum Stabiliser Long ref 4131 | Ortho Medico | | | | | | |
| | OBJECT kniebandage M.808 | Distrac | | | | | | |
| | Air Donjoy 11-0663, | Dirame | | | | | | |
| | Donjoy Lateral J 11-0320-0321-0659-0660 | Dirame | | | | | | |
| | Donjoy H-butress032-322-323-432-324-325 | Dirame | | | | | | |
| | DonjoyDeluxe donut 327-328-380-381 | Dirame | | | | | | |
| | Horse Shoe 11-0334, 0342, 0344, 0343 | Dirame | | | | | | |
| | Royce 3 Pannel | Ortimex | | | | | | |
| | OTHER PRODUCTS | | | | | | | |

| Nomenclature code | Product | Distributor | Number of products sold / year | If no exact number TOP-10 most sold products | Purchase price from manufacturer | Selling price excl VAT | Your provider | Cheapest product known |
|-------------------|--|---------------|--------------------------------|--|----------------------------------|------------------------|---------------|------------------------|
| Knee | Donjoy Kniebrace Donjoy | | | | | | | |
| 647533 | Donjoy Drytec | | | | | | | |
| | Hinged Knee Economy réf.11-0372 | Donjoy | | | | | | |
| | Genutrain S | Bauerfeind | | | | | | |
| | Thuasne Ligaflex Evolution | Thuasne | | | | | | |
| | Thuasne Ligaflex 2370 | Thuasne | | | | | | |
| | Hinged knee support | Ortimex | | | | | | |
| | Wrap around knee support | Ortimex | | | | | | |
| | Genu Flex 8151 | Otto Bock BNL | | | | | | |
| | Genu EQ combi stable réf.2262 | Otto Bock BNL | | | | | | |
| | Genu Lock 8152 | Otto Bock BNL | | | | | | |
| | Genu Combi basis 8153 | Otto Bock BNL | | | | | | |
| | Genu Stable 2259 | Otto Bock BNL | | | | | | |
| | Short Runner | Pabisch | | | | | | |
| | PTO (patellar tracking orthosis) | Pabisch | | | | | | |
| | Bledsoe Sportmax - ref 3175 | Ortho Medico | | | | | | |
| | DeRoyal Genum Liga (T3) - ref EU 4112 | Ortho Medico | | | | | | |
| | DeRoyal Genum Liga ACL (T3) - ref 4110 | Ortho Medico | | | | | | |
| | Donjoy Tru-Pull hinged sleeve | Sprofit | | | | | | |
| | Hinged Knee Bioskin | Somas Orth | | | | | | |
| | Stabimed II Pro | medi | | | | | | |
| | Airtex hinged knee pro | medi | | | | | | |
| | Stabimed II | medi | | | | | | |
| | Airtex hinged knee wrap | medi | | | | | | |
| | protect.Co | medi | | | | | | |
| | protect.St | medi | | | | | | |
| | protect.St pro | medi | | | | | | |
| | protect.OA soft | medi | | | | | | |
| | Bort Knee Bandage 114460 | Axamed | | | | | | |
| | Bort Knee Bandage 114480 | Axamed | | | | | | |
| | Bort Stabilo 150140 | Axamed | | | | | | |
| | OBJECT Kniebandage M.815 | Distrac | | | | | | |
| | Elcross réf. 124,126, 128 en vlg | Dirame | | | | | | |
| | Economy hinged knee | Dirame | | | | | | |
| | Drytex economy hinged knee 11-0671 | Dirame | | | | | | |
| | Opal | Dirame | | | | | | |
| | Tru Pull hinged | Dirame | | | | | | |
| | G II Trainer | Össur | | | | | | |
| | OTHER PRODUCTS | | | | | | | |

DETAILED RESULTS OF THE PRODUCTS SOLD ON THE BELGIAN MARKET

Prefab hard knee brace hinged (nomenclature code 647592)

Table 2: Knee nomenclature code 647592: distributors / products sold in 2006

| KNEE Nomenclature code 647592: Products | Distributor Belgium | Number of products sold/Year Belgium (2006) |
|--|---------------------|---|
| Bledsoe Aligner ESE L/R | Ortho-Medico | 988 |
| Bledsoe Axiom L/R | Ortho Medico | 948 |
| Donjoy 4-titude | Sprofit | 874 |
| Donjoy grouped number | Dirame | 660 |
| Donjoy Legend Funct. brace ACL | Sprofit | 642 |
| C.Ti.2 | Somas | 350 |
| Generation II unloader adj. | Ossur | 350 |
| Donjoy OAdjuster | Sprofit | 344 |
| Bauerfeind SecuTec® Genu LR | Bauerfeind | 319 |
| Bauerfeind MOS Genu® Short (court + long) | Bauerfeind | 269 |
| THUASNE GENU PRO Control Clasic | Thuasne | 259 |
| Bledsoe Thruster (medial - lateral) RLF L/R | Ortho Medico | 183 |
| Medi M.4® CI or ACL or PCL | Medi | 134 |
| Otto Bock Genu Arthro - 28K20/28K21 | Otto Bock BNL | 50 |
| Bledsoe Ultimate Dynamic L/R | Ortho Medico | 43 |
| Otto Bock Genu arexa- 50K13 | Otto Bock BNL | 25 |
| Medi M.4 ® OA (osteoarthritis barce) | Medi | 20 |
| Donjoy Fource point (Defiance) | Sprofit | 15 |
| Bledsoe Axiom Brace Black L/R | Ortho Medico | 7 |
| Bledsoe Axiom custom L/R | Ortho Medico | 1 |
| Bort OTS Knee Brace 100600 | Axamed | 0 |
| | TOTAL | 6.481 |
| Number of RIZIV/INAMI reimbursed cases (2005) = 6.678 | | |

Source: Survey to distributors

Prefab knee bandage woven reinforced (nomenclature code 647555)

Table 3: Knee nomenclature code 647555 distributors / products sold in 2006

| | | |
|---|--------------|---------------|
| Bauerfeind Genutrain® | Bauerfeind | 10.092 |
| Bauerfeind Genutrain® P3 | Bauerfeind | 3.124 |
| Bauerfeind Genutrain® A3 | Bauerfeind | 1.503 |
| Push Med knee | Vitamed | 605 |
| Push Care knee | Vitamed | 328 |
| Thuasne Silistab Genu | Thuasne | 261 |
| Otto Bock Genu Sensa 50K15 | Otto Bock | 250 |
| Medi.ortho Genumedi® | Medi | 250 |
| OM-IMMOB knee immobilizer | Ortho Medico | 233 |
| Medi.ortho elastic knee support 603 | Medi | 150 |
| Otto Bock Knee Support Basic-8953 | Otto Bock | 140 |
| DeRoyal SPORT Knee brace ref 8052 | Ortho Medico | 130 |
| Genu Carezza Patella stabiliser-8360 | Otto Bock | 70 |
| Bort Knee Bandage 114 150 | Axamed | 57 |
| Medi.ortho elastic knee support 605 | Medi | 50 |
| Otto Bock Genu Carezza-8358 | Otto Bock | 40 |
| DeRoyal Genum Stabiliser Long Silicon(T3) | Ortho Medico | 36 |
| Otto Bock Genu Basis Open-7154 | Otto Bock | 30 |
| Otto Bock Genu Carezza Wraparound-8362 | Otto Bock | 30 |
| Otto Bock Genu Chondro-7155 | Otto Bock | 30 |
| Otto Bock Genu Lux-7158 | Otto Bock | 25 |
| Otto BockGenu Thema-8361 | Otto Bock | 20 |
| Otto Bock Knee Support relieving pad-7058 | Otto Bock | 20 |
| Otto Bock Genu Thema Fit-8354 | Otto Bock | 15 |
| Bort Stalobogen Patella Knee Brace 114 420 | Axamed | 14 |
| DeRoyal Genum Stabiliser Long (T3) EU 4131 | Ortho Medico | 14 |
| Otto Bock Genu Thema Patella-8364 | Otto Bock | 10 |
| Otto Bock Genu Basis-7151 | Otto Bock | 10 |
| Otto Bock Genu ComforT-8255 | Otto Bock | 10 |
| Otto Bock Genu Flex-8151 | Otto Bock | 10 |
| Otto Bock Genu Tendon-7107 | Otto Bock | 10 |
| Bort Stabilogen ECO Patella brace 114 520 | Axamed | 5 |
| Bort Stabilo Knee Bandage 2 stays 114 450 | Axamed | 4 |
| Bort Knee Support EXTRA large 114 490 | Axamed | 4 |
| | TOTAL | 17.580 |
| Number of RIZIV / INAMI reimbursed cases (2005) = 12.727 | | |

**Prefab knee brace elastic tissue or neoprene reinforced with metal
(nomenclature code 647533)**

**Table 4: Knee nomenclature code 647533 distributors / products sold
2006**

| KNEE Nomenclature code 647533: Products | Distributor Belgium | Number of products sold/Year Belgium (2006) |
|--|--------------------------------|--|
| Bauerfeind Genutrain® S | Bauerfeind | 2.011 |
| Thuasne Ligaflex Evolution | Thuasne | 1.184 |
| Thuasne Ligaflex 2370 | Thuasne | 1.036 |
| Donjoy Drytec | Sprofit | 342 |
| Elcross réf. 124,126, 128 grouped number | Dirame | 300 |
| MEDI hinged knee PRO (airtex) | Medi | 160 |
| DeRoyal Genum Liga (T3) - ref EU 4112 | Ortho Medico | 115 |
| Donjoy Tru-Pull hinged sleeve | Sprofit | 96 |
| Otto Bock Genu Track - 50K20 | Otto Bock | 60 |
| Otto Bock Genu Direxa Stable Wraparound - 8367 | Otto Bock | 60 |
| Otto Bock Genu Immobil - 8060/8062 | Otto Bock | 50 |
| MEDI hinged knee wrap (airtex) | Medi | 45 |
| Otto Bock Genu Direxa Stable - 8357 | Otto Bock | 40 |
| MEDI Stabimed® Pro II | Medi | 35 |
| Otto Bock Genu Stable Long Wraparound - 8368 | Otto Bock | 30 |
| MEDI Stabimed® II | Medi | 23 |
| Otto Bock Genu Direxa - 8356 | Otto Bock | 20 |
| Otto Bock Genu Lock - 8152 | Otto Bock | 15 |
| Otto Bock Genu Combi Stable - 8156 | Otto Bock | 15 |
| Bort Knee Bandage with articulated joint 114 460 | Axamed | 11 |
| Otto Bock Genu Direxa Wraparound - 8353 | Otto Bock | 10 |
| Otto Bock Genu Stable - 7159 | Otto Bock | 10 |
| Otto Bock Genu Comfort Stable - 8256 | Otto Bock | 10 |
| Otto Bock Genu Combi Basis - 8153 | Otto Bock | 10 |
| Otto Bock Genu Direxa Stable Long - 8359 | Otto Bock | 10 |
| Otto Bock Genu Immobil Vario - 8065 | Otto Bock | 10 |
| Bledsoe Sportmax - ref 3175 | Ortho Medico | 6 |
| Bort Stabilo Knee bandage with Hinge 150 140 | Axamed | 5 |
| Hinged Knee Economy réf.11-0372 | Sprofit | 2 |
| | TOTAL | 5.721 |
| Number of RIZIV/INAMI reimbursed cases (2005) = 4.834 | | |

Prefab soft collar (nomenclature code 645175)

Table 5: Neck nomenclature code 645175 distributors / products sold 2006

| Neck Nomenclature code 645175: Products | Distributor Belgium | Number of products sold/Year Belgium (2006) |
|--|---------------------|---|
| Thuasne Ortel (zacht)2390 ORTEL C1 | Thuasne | 2.118 |
| GLOBOMEDIC Bauerfeind | Bauerfeind | 1.719 |
| Thämert 49/190 | Axamed | 1.691 |
| Push Care 8 cm en 10 cm | Vitamed | 1.288 |
| Push nek Med 8 cm en 10 cm | Vitamed | 1.274 |
| Basco Camp grouped number | Dirame | 950 |
| DeRoyal Foam cervical collar 6/8/10/12cm ref EU 515 | Ortho-Medico | 837 |
| Otto Bock Necky Color - 50C20 | Otto Bock | 685 |
| Otto Bock Necky Anatomic - 103 - 104 - 105 | Otto Bock | 255 |
| Bort Cervical Support beige 127 360 | Axamed | 112 |
| Otto Bock Necky Color Forte - 50C30 | Otto Bock | 100 |
| Philadelphia Cervical Orthosis - 50C40 | Otto Bock | 50 |
| Bort Stabilo cervical support 127 160 | Axamed | 36 |
| Medi@ protect collar soft 7-9cm | Medi | 20 |
| Bort Cervical Support white 127 260 | Axamed | 15 |
| Bort Stabilonec with reinforcement brace 127 560 | Axamed | 2 |
| | TOTAL | 11.152 |
| Number of RIZIV / INAMI reimbursed cases (2005) = 6.939 | | |

Source: Survey to distributors

Prefab wrist bandage, reinforced limiting movement (nomenclature code nr. 649434)

Table 6: Wrist nomenclature code 649434 distributors / products sold 2006

| Wrist Nomenclature code 649434: Products | Distributor Belgium | Number of products sold/Year Belgium (2006) |
|---|----------------------------|--|
| Push Med wrist | Vitamed | 5.820 |
| Bort wrist support aluminium splint 103 300 | Axamed | 2.715 |
| medi Wrist support | Medi | 1.866 |
| Elastic wrist brace Donjoy | Sprofit | 1.690 |
| Bauerfeind ManuTrain® | Bauerfeind | 1.124 |
| Manu Rheuma Flex - 4142 | Otto Bock | 810 |
| Push Med Splint wrist | Vitamed | 779 |
| Basko Elcross grouped number | Dirame | 730 |
| DeRoyal - Manex Reuma Pollus - ref EU 2025 | Ortho Medico | 536 |
| Bauerfeind ManuLoc® | Bauerfeind | 474 |
| Push Care wrist | Vitamed | 456 |
| Manu 3D Pollex - 4146 | Otto Bock | 450 |
| Ultimate Wrist Support | Distrac | 400 |
| Diagonal Short - 4074 | Otto Bock | 350 |
| MEDI Manumed | Medi | 238 |
| DeRoyal - Manex Reuma Long - ref EU2024 | Ortho Medico | 234 |
| Wrist Support Brace - 8910 | Otto Bock | 170 |
| Bort Sellatex 112 050 | Axamed | 165 |
| Rolyan D-Ring wrist+thumb | Sprofit | 154 |
| Manu 3D Stable - 4145 | Otto Bock | 100 |
| Donjoy Thumb-o-prene | Sprofit | 93 |
| Manu 3D Basis - 4143 | Otto Bock | 90 |
| Manu Rheuma Pollex - 4025 | Otto Bock | 75 |
| Thumbofrom Long - 4085 | Otto Bock | 30 |
| Manu Forsa Volar - 50P12 | Otto Bock | 30 |
| Manu 3D Short - 4103 | Otto Bock | 25 |
| Wrist Support Child - 4067 | Otto Bock | 25 |
| Manu EQ Soft - 404 | Otto Bock | 25 |
| Manu ComforT Stable - 4058 | Otto Bock | 25 |
| Manu ComforT - 4055 | Otto Bock | 20 |
| Manuell EQ - 4062 | Otto Bock | 20 |
| Manu Immobil - 50P10 | Otto Bock | 20 |
| Wrist Positioning Orthosis - 28P44 | Otto Bock | 20 |
| Silicon Wrist Orthosis - 28P10/20 | Otto Bock | 20 |
| Bort Manuzip volar 112 220 | Axamed | 12 |
| Thumboform Short - 4084 | Otto Bock | 10 |
| Wrist Immobilization Orthosis 28P48 | Otto Bock | 10 |
| Wrist Orthosis, Short - 28P42 | Otto Bock | 10 |
| Wrist Orthosis, Long - 28P40 | Otto Bock | 10 |
| TOTAL | | 19.831 |
| Number of RIZIV/INAMI reimbursed cases (2005) = 12.376 | | |

Source: Survey to distributors

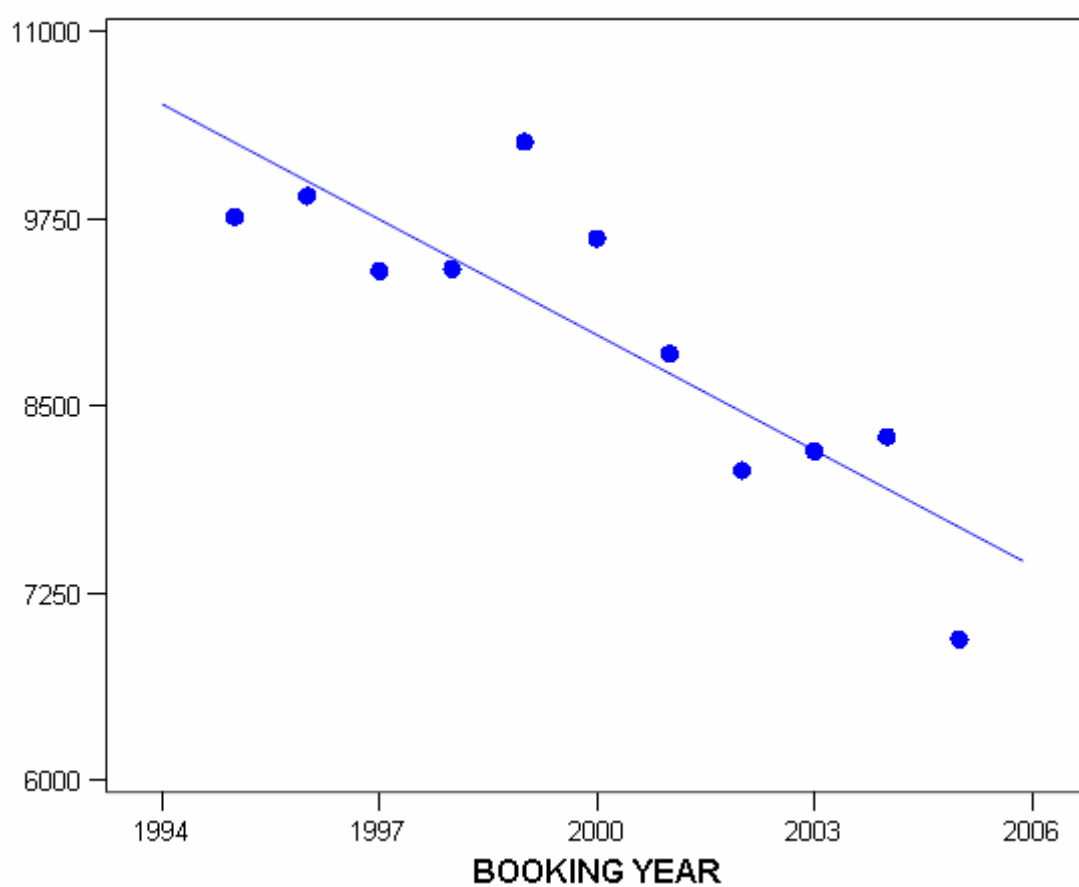
Booked quantities in Product scope for 2006

Forecasts based on OLS regressions per billing code (SAS Eguide Output)
RIZIVcode=645175

| | | | |
|-----------------------|------------|-----------------|--------|
| Root MSE | 548.94720 | R-Square | 0.7279 |
| Dependent Mean | 8971.27273 | Adj R-Sq | 0.6977 |
| Coeff Var | 6.11894 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | 522644 | 104680 | 4.99 | 0.0007 |
| BOOKING YEAR | 1 | -256.83636 | 52.34006 | -4.91 | 0.0008 |
| | | | | | |

NUMBER OF DEVICES

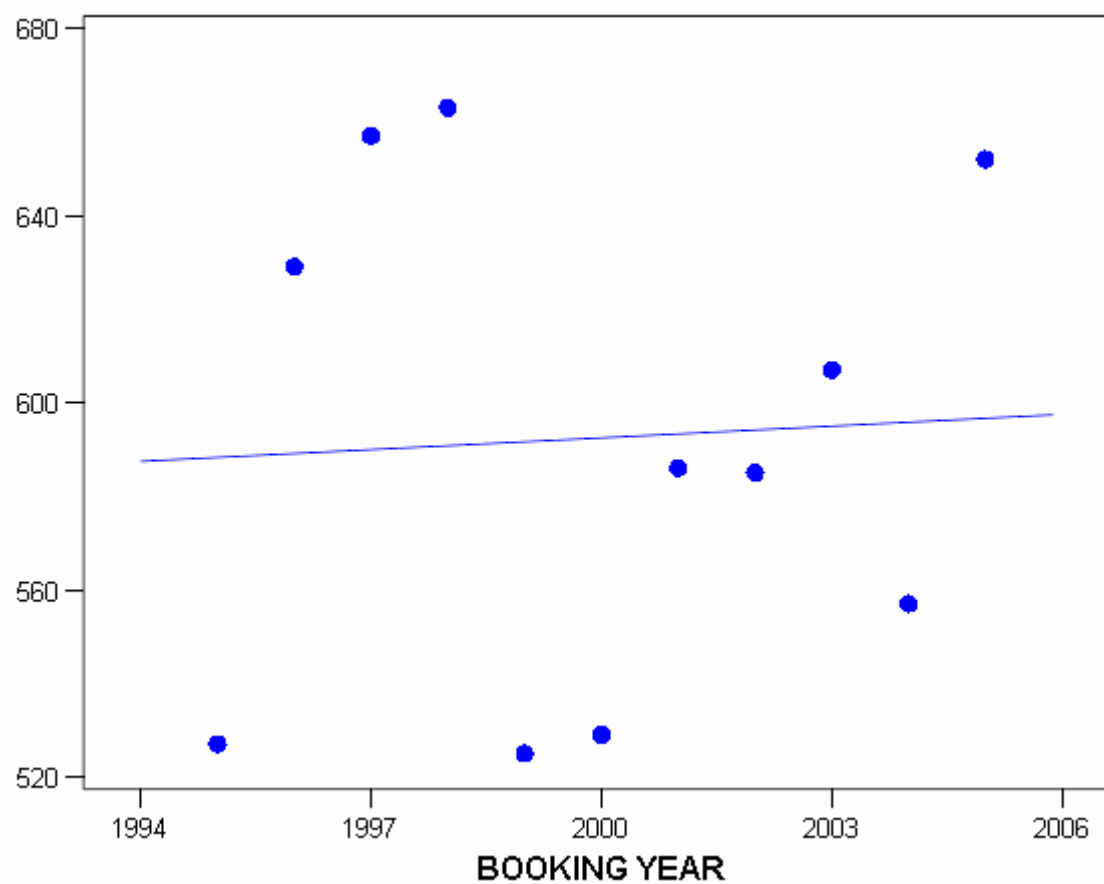


RIZIVcode=645212

| | | | |
|-----------------------|-----------|-----------------|---------|
| Root MSE | 56.14840 | R-Square | 0.0027 |
| Dependent Mean | 592.45455 | Adj R-Sq | -0.1081 |
| Coeff Var | 9.47725 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | -1080.27273 | 10707 | -0.10 | 0.9218 |
| BOOKING YEAR | 1 | 0.83636 | 5.35354 | 0.16 | 0.8793 |

NUMBER OF DEVICES

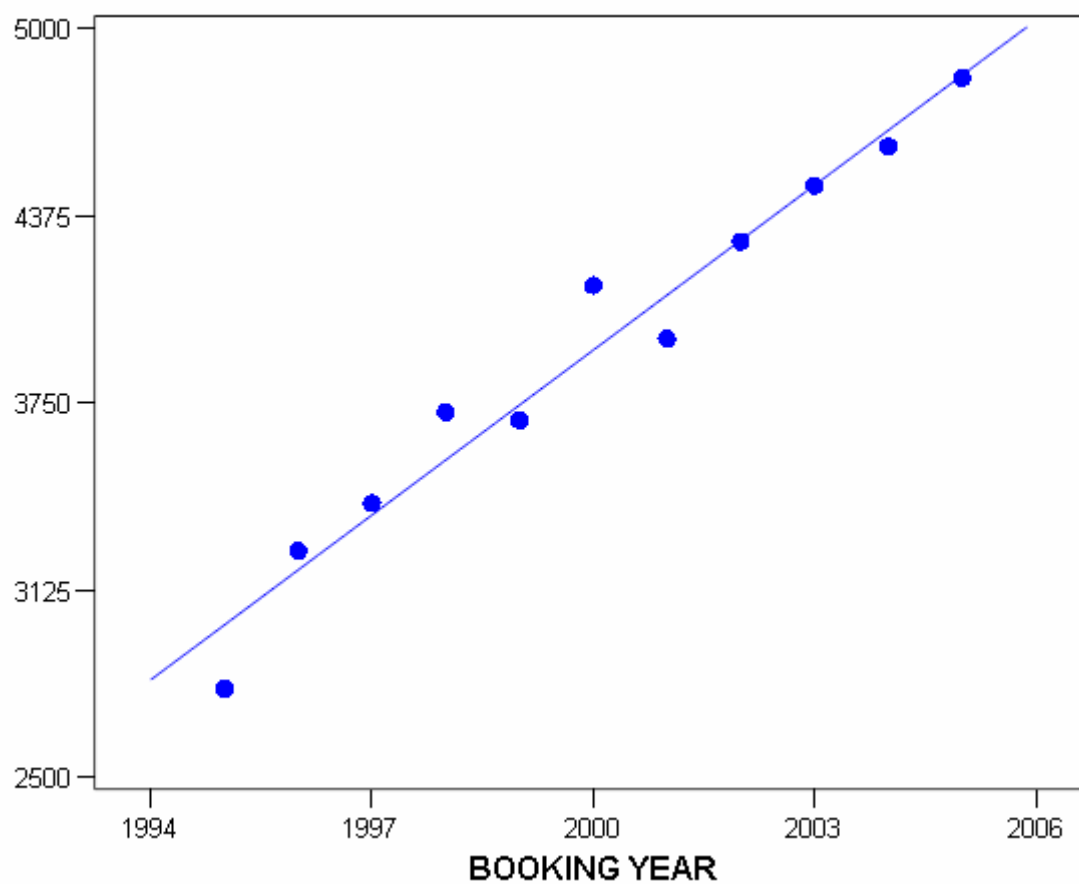


RIZIVcode=647533

| | | | |
|-----------------------|------------|-----------------|--------|
| Root MSE | 128.90367 | R-Square | 0.9612 |
| Dependent Mean | 3925.09091 | Adj R-Sq | 0.9569 |
| Coeff Var | 3.28409 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | -363075 | 24581 | -14.77 | <.0001 |
| BOOKING YEAR | 1 | 183.50000 | 12.29048 | 14.93 | <.0001 |

NUMBER OF DEVICES

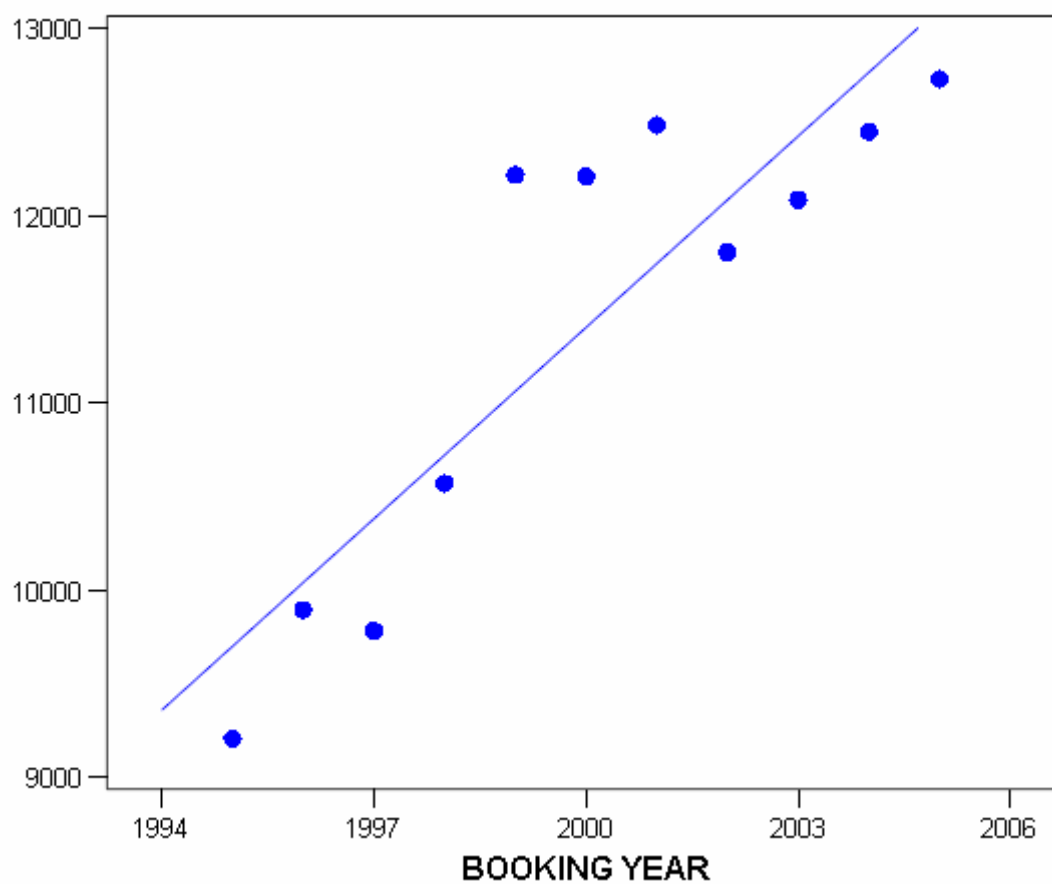


RIZIVcode=647555

| | | | |
|-----------------------|-----------|-----------------|--------|
| Root MSE | 634.32182 | R-Square | 0.7791 |
| Dependent Mean | 11401 | Adj R-Sq | 0.7546 |
| Coeff Var | 5.56365 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | -670126 | 120961 | -5.54 | 0.0004 |
| BOOKING YEAR | 1 | 340.76364 | 60.48021 | 5.63 | 0.0003 |

NUMBER OF DEVICES

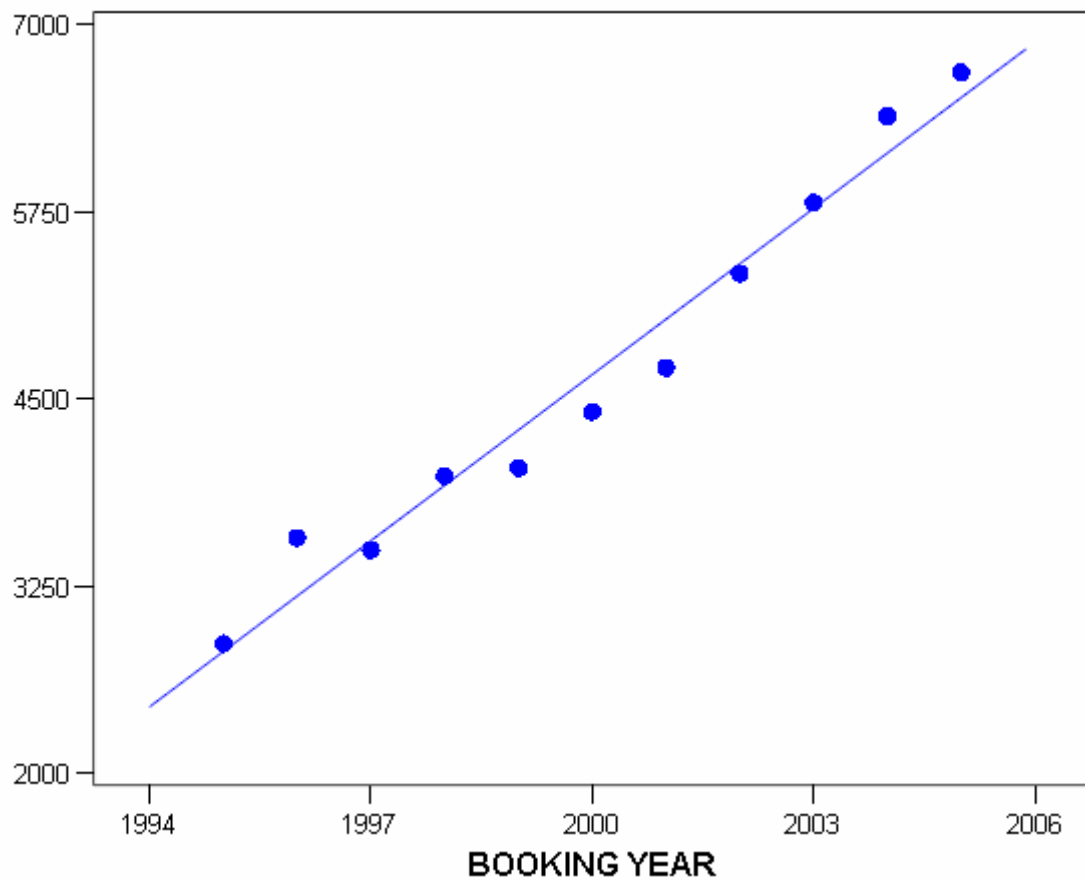


RIZIVcode=647592

| | | | |
|-----------------------|------------|-----------------|--------|
| Root MSE | 232.80267 | R-Square | 0.9686 |
| Dependent Mean | 4660.18182 | Adj R-Sq | 0.9651 |
| Coeff Var | 4.99557 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | -734740 | 44394 | -16.55 | <.0001 |
| BOOKING YEAR | 1 | 369.70000 | 22.19686 | 16.66 | <.0001 |

NUMBER OF DEVICES

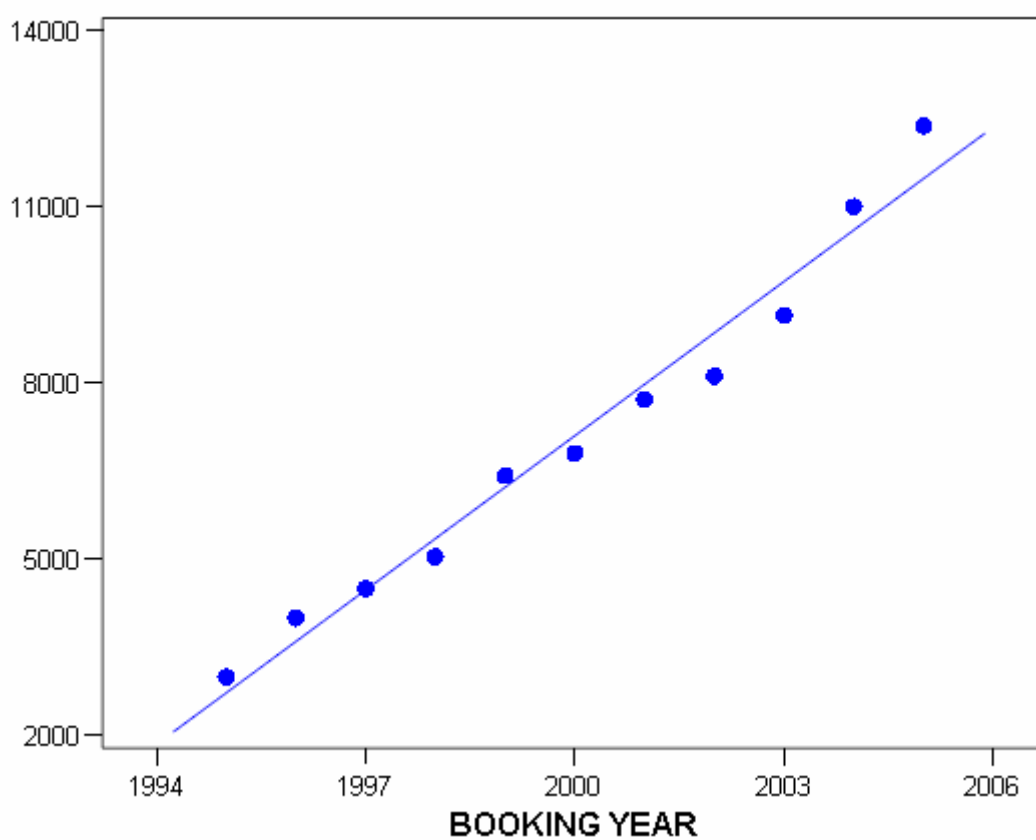


RIZIVcode=649434

| | | | |
|-----------------------|------------|-----------------|--------|
| Root MSE | 512.41888 | R-Square | 0.9727 |
| Dependent Mean | 7103.81818 | Adj R-Sq | 0.9697 |
| Coeff Var | 7.21329 | | |

| Parameter Estimates | | | | | |
|---------------------|----|--------------------|----------------|---------|---------|
| Variable | DF | Parameter Estimate | Standard Error | t Value | Pr > t |
| Intercept | 1 | -1742533 | 97715 | -17.83 | <.0001 |
| BOOKING YEAR | 1 | 874.81818 | 48.85722 | 17.91 | <.0001 |

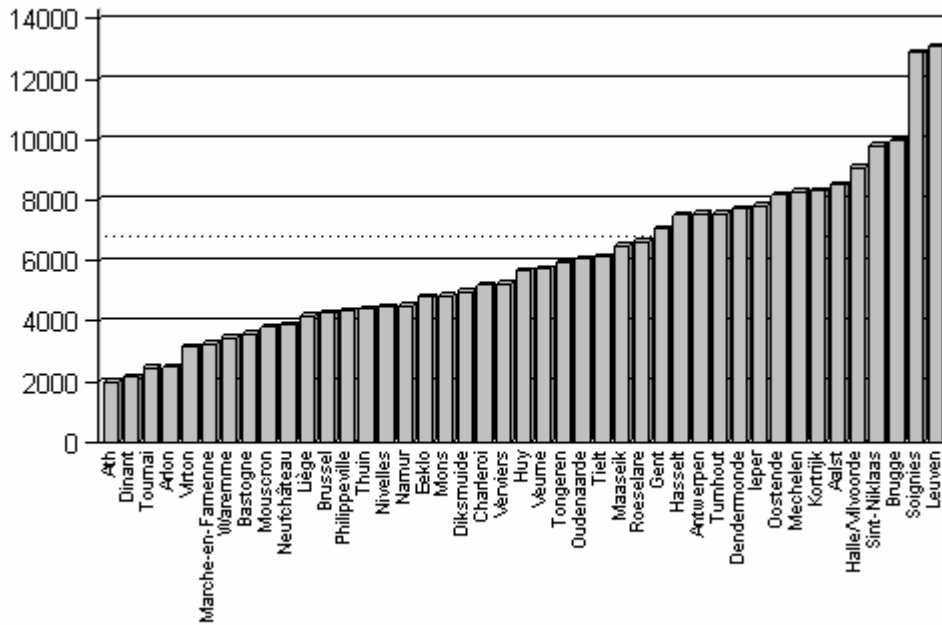
NUMBER OF DEVICES



Geographic utilisation patterns scoped products (by billing code)

BILLING CODE 647592 (BELGIUM = 6678 CASES = 100)

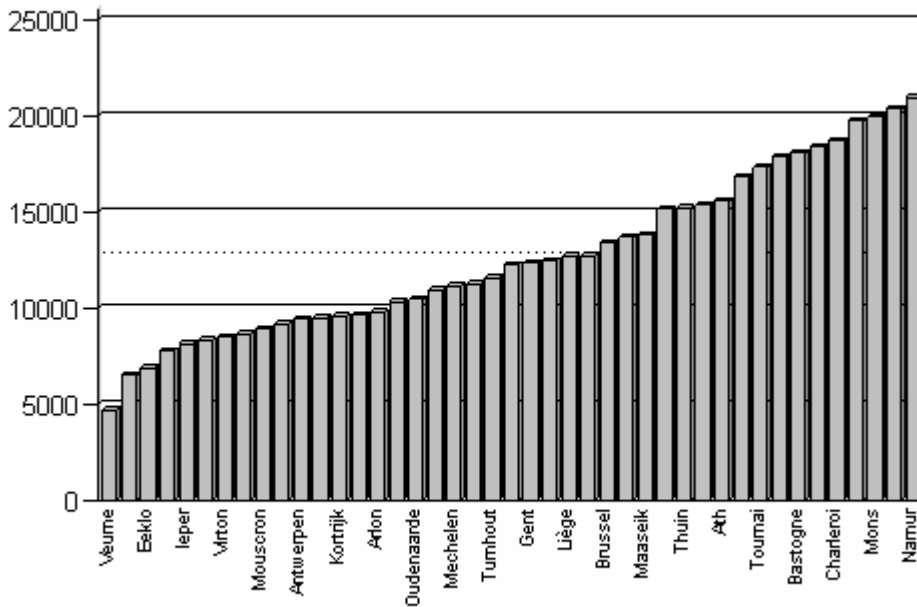
CASES



REGION

BILLING CODE 647555 (BELGIUM = 12727 CASES = 100)

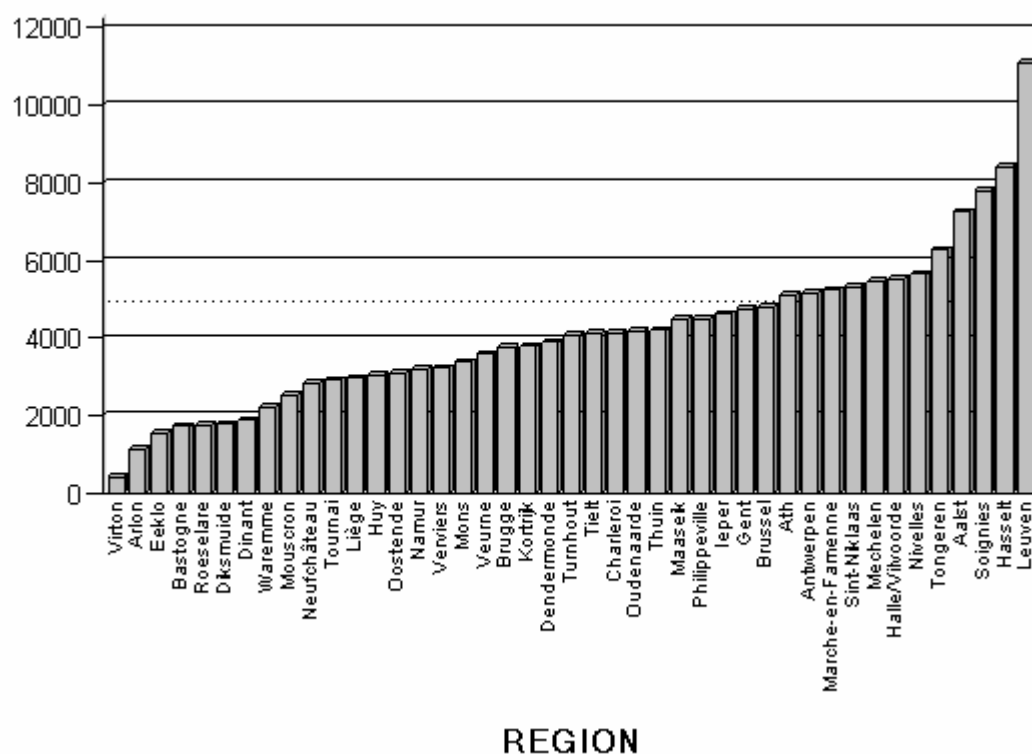
CASES



REGION

BILLING CODE 647533 (BELGIUM = 4834 CASES = 100)

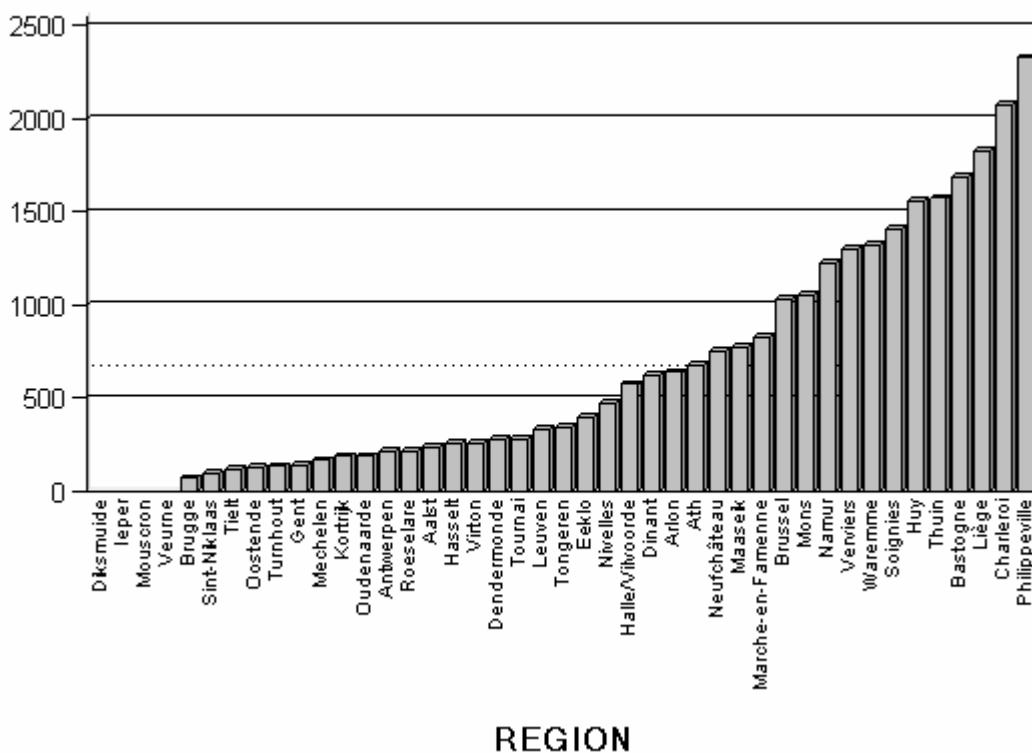
CASES



REGION

BILLING CODE 645212 (BELGIUM = 652 CASES = 100)

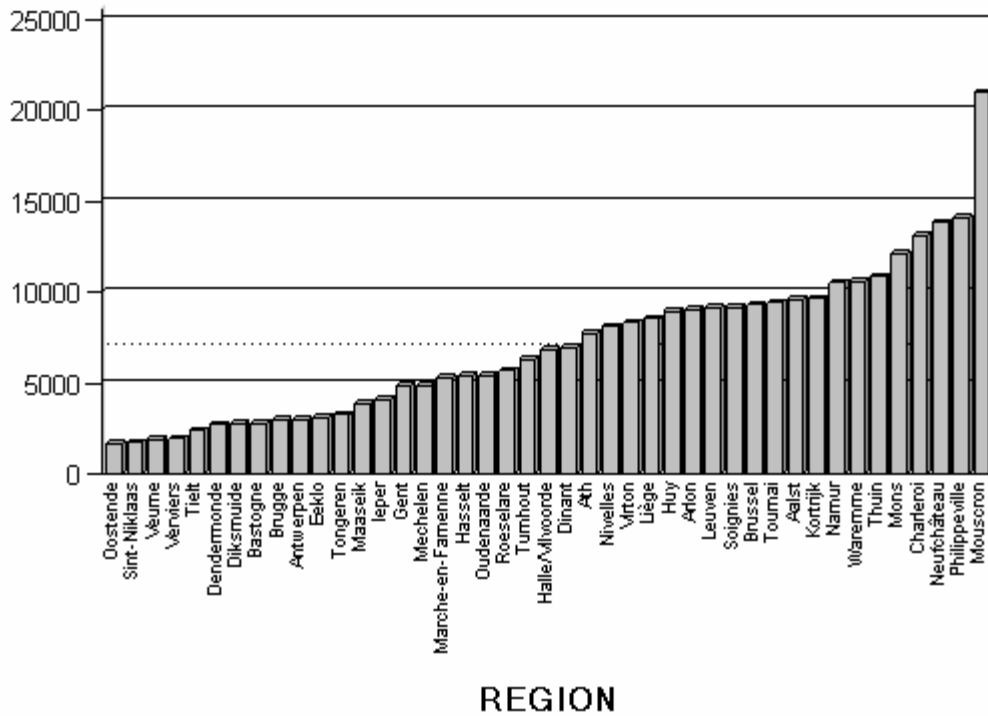
CASES



REGION

BILLING CODE 645175 (BELGIUM = 6939 CASES = 100)

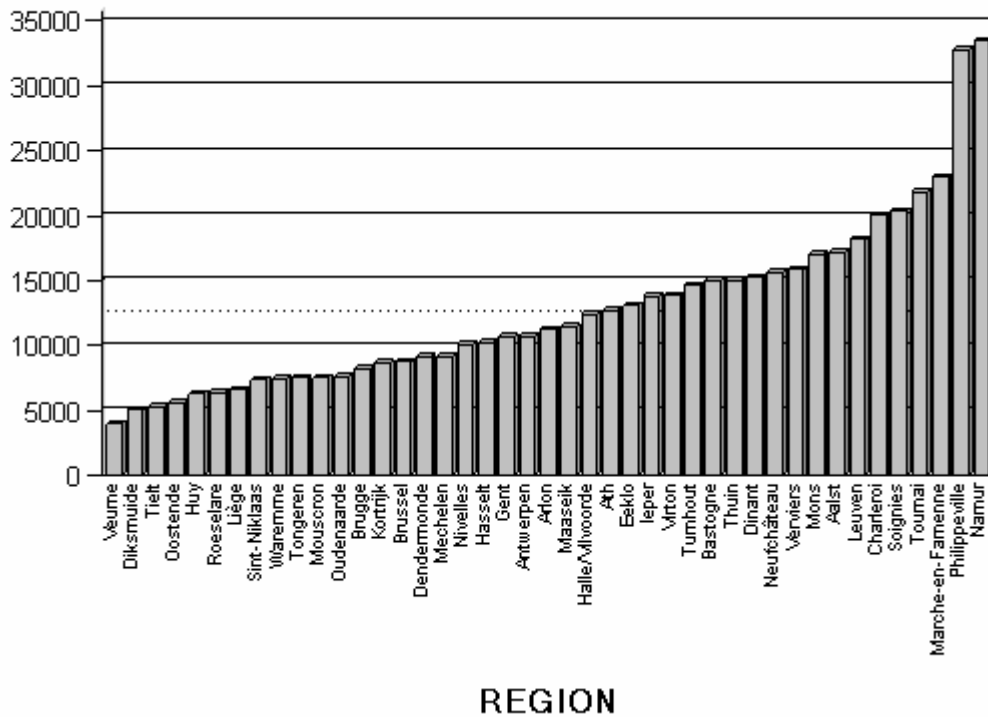
CASES



REGION

BILLING CODE 649434 (BELGIUM = 12376 CASES = 100)

CASES



REGION

List of Distributors on the belgian market

| Distributors Belgium | | |
|-----------------------------|---|--|
| Aircast Belgium Bvba | Drukpersstraat 4 1000 Brussel | www.aircast.be |
| Axamed | Industriepark West 58 9100 St Niklaas | www.axamed.be |
| Bauerfeind Benelux BV | Waarderveldweg 1 2031 BK Haarlem Netherlands | www.bauerfeind.nl |
| Dirame Orthopedie NV | Assesteenweg 27 -29 1740 Ternat | www.dirame.be |
| Distrac NV | Bleyveld 14 3320 Hoegaarden | www.distrac.com |
| Medi Belgium | Voortstraat 79 3580 Beringen | www.medibelgium.be |
| Ortho-Medico | Mutsaardstraat 47 9550 Herzele | www.lasermedico.be |
| Ortimex | Herentalsebaan 417A 2160 Wommelgem | www.ortimex.be |
| Ossur Europe | Ekkersrijt 4112-4114 5690 AC Son en Breugel Netherlands | www.ossur.com |
| Otto Bock Benelux BV | Ekkersrijt 1412 5692 AK Son en Breugel | www.ottobock.com |
| Somas Orthopedie | t Kempke 1 5845 GB Sint Anthonis Netherlands | www.somas.nl |
| SproFit bvba | Transportlaan 9 - 3600 Genk | www.sprofit.com |
| Thuasne Belgilux NV | Intercity Businesspark Gen. de Wittelaan 17 2800 Mechelen | www.thuasne.com |
| Vitamed | Vriesenrot 3 9200 Dendermonde | www.vitamed.be |
| | | |

List of Distributors interviewed

| Distributors Belgium | | | |
|-----------------------------|---|--------------------------------------|-------------------------|
| Axamed | Industriepark West 58 9100 St Niklaas | Dhr. Marc Vergauwen | Sales&Marketing Manager |
| Bauerfeind Benelux BV | Waarderveldweg 1 2031 BK Haarlem Netherlands | Dhr. B. Dieleman | General Manager |
| Medi Belgium | Voortstraat 79 3580 Beringen | Dhr. Luc Schols | Managing Director |
| Ortho-Medico | Mutsaardstraat 47 9550 Herzele | Dhr. Jo Schops Dhr. Geert Meskens | Vice President COO |
| Thuasne Belgilux NV | Intercity Businesspark Gen. de Wittelaan 17 2800 Mechelen | Dhr. Alain Neckebroek | Commercieel Directeur |
| Vitamed | Vriesenrot 3 9200 Dendermonde | Dhr. Jacques Smet | Gedelegeerd bestuurder |

APPENDIX TO CHAPTER V

List of products for price comparison

| Nomenci. code/ | Product | Patient Price incl.VAT (1) | % VAT | Amount reimbursed (or at charge of health security system) | |
|--|---|-------------------------------------|-------|---|--|
| KNEE 647592 | Bledsoe Aligner ESE L/R | | | | |
| | Bledsoe Axiom Sport L/R | | | | |
| | Bauerfeind SecuTec® Genu LR | | | | |
| | Bauerfeind MOS Genu® long | | | | |
| | Bauerfeind MOS Genu® Short (number =s+ l) | | | | |
| | Donjoy Legend Funct. brace ACL | | | | |
| | Donjoy 4-titude | | | | |
| | THUASNE GENU PRO Control Clasic | | | | |
| | C.Ti.2 (OSSUR) | | | | |
| | Generation II unloader adj (OSSUR) | | | | |
| | Medi M.4® CI or ACL or PCL | | | | |
| | Medi M.4 ® OA (osteoarthritis barce) | | | | |
| | Bort OTS Knee Brace 100600 | | | | |
| | KNEE 647555 | Bauerfeind Genutrain® | | | |
| | | Bauerfeind Genutrain® P3 | | | |
| Bauerfeind Genutrain® A3 | | | | | |
| Push Care knee | | | | | |
| Push Med knee | | | | | |
| Thuasne Silistab Genu | | | | | |
| Otto Bock Knee Support Basic-8953 | | | | | |
| Otto Bock Genu Sensa 50K15 | | | | | |
| Medi.ortho Genumedi® | | | | | |
| Medi.ortho elastic knee support 603 with 2 pairs balleines spiral | | | | | |
| DeRoyal SPORT Knee brace with flexible springs ref 8052 | | | | | |
| DeRoyal Genum Stabiliser Long Silicon beige(T3) - ref EU 4332 | | | | | |
| Donjoy Patella Knee Support Lateral J 11-0320, 0321, 0659, 0660 | | | | | |

| | | | | |
|--------------------|--|--|--|--|
| Knee 647533 | Donjoy Drytec | | | |
| | Bauerfeind Genutrain® S | | | |
| | Thuasne Ligaflex Evolution | | | |
| | Thuasne Ligaflex 2370 | | | |
| | Otto Bock Genu Track - 50K20 | | | |
| | Otto Bock Genu Direxa Stable Wraparound - 8367 | | | |
| | DeRoyal Genum Liga (T3) - ref EU 4112 | | | |
| | Donjoy Tru-Pull hinged sleeve | | | |
| | MEDI hinged knee PRO (airtex) | | | |
| | | | | |
| NECK 645212 | Jerome Miami J.Collar | | | |
| | Malibu halskraag 06/3020 | | | |
| | Fillauer/Basko Ortho-Collar 105320 | | | |
| Neck 645175 | Push Care 8 cm en 10 cm | | | |
| | Push nek Med 8 cm en 10 cm | | | |
| | Thuasne Ortel C1(zacht) 2390 ORTEL C1 | | | |
| | GLOBOMEDIC Bauerfeind | | | |
| | Basco Camp grouped number | | | |
| | Basko Camp 5750, 5700, 5800 | | | |
| | Basko Camp 5620/21, 5720/21, 5820/21 | | | |
| | Thämert 49/190 | | | |
| | Bort Cervical Support beige 127 360 | | | |
| | | | | |
| | DeRoyal Foam cervical collar 6/8/10/12cm ref EU 515 | | | |
| | Otto Bock Necky Color - 50C20 | | | |

| | | | | |
|---|---|--|--|--|
| WRIST 649434 | Bauerfeind ManuLoc® | | | |
| | Bauerfeind ManuTrain® | | | |
| | Push Med wrist | | | |
| | Push Care wrist | | | |
| | Donjoy Elastic wrist brace | | | |
| | medi Wrist support | | | |
| | Bort wrist support with aluminium splint 103 300 | | | |
| | DeRoyal - Manex Reuma Long - ref EU2024 | | | |
| | DeRoyal - Manex Reuma Pollus - ref EU 2025 | | | |
| | Basko Elcross Carpus Midi 0141 grouped number | | | |
| | Basko Elcross Carpus Flexi 144 | | | |
| | Manu Rheuma Flex - 4142 Otto Bock | | | |
| (1) Patient price is included VAT and inclusive eventual (partial) reimbursement by social security system | | | | |

APPENDIX TO CHAPTER VI

Questionnaire towards manufacturers

This questionnaire is focused on orthopaedic prefab braces – hard knee braces & hard neck braces

General Market information

1. What is the importance of orthopaedic prefab braces for your company?
 - % of turn-over
 - % of personnel involved
2. How would you estimate the proportion between tailor made and standard prefab orthopaedic braces? If this proportion is very different for hard knee and hard neck braces, please specify
 - % of production is tailor-made, answering specific client needs
 - % of production is standard, prefab production
 -
 -
3. What is your market share for prefab orthopaedic braces in the following countries? If detailed information is available for the subgroups please fill in column 2 and 3

| | Prefab orthopaedic braces (overall) | Hard knee braces | Hard neck braces |
|-------------|-------------------------------------|------------------|------------------|
| Belgium | | | |
| Sweden | | | |
| France | | | |
| Netherlands | | | |
| U.K. | | | |
| Canada | | | |

4. Cost structure: Could you give us an indication on the importance of the different elements of the production cycle for orthopaedic prefab braces?
 - Please indicate these as an average % of the total production cost.
 - Detailed information on representative products of the indicated categories can be added in the following columns.
 - Please specify the name of these products.

| | Overall Prefab orthotic devices | Prefab hard knee braces | Prefab hard neck braces |
|----------------------------------|--|----------------------------|----------------------------|
| Product name | | | |
| Research and development * | | | |
| Raw Material ** | | | |
| Manufacturing process *** | | | |
| Labour | | | |
| Capital /machinery | | | |
| Energy and utilities | | | |
| Engineering | | | |
| Maintenance and repair | | | |
| Quality assurance and control | | | |
| Warehousing | | | |
| Distribution / transport | | | |
| Marketing | | | |
| Others | | | |
| Total production cost | 100 % | 100 % | 100 % |

* Research & Development

I. Can you give us an indication on the following R&D matters concerning orthopaedic prefab braces?

- Budget for R&D activities. (% of turn-over)

- Number of people directly involved in R&D activities

- Number of “patents” related to orthopaedic prefab braces for your company

- What is the average development time for orthopaedic prefab braces at your company (e.g. time passing before an innovative product for an existing pathology will be launched?)

- What share of research projects is successful and leads to beneficial commercialisation? (%)

** Raw material

- I. Can you list the raw materials with the highest impact on the total material cost, and indicate their share of total material cost?

Please apply for the most representative products

| Prefab hard knee braces | Most important raw materials | Share of total material cost |
|-------------------------|------------------------------|------------------------------|
| | | |
| | | |

| Prefab hard neck braces | Most important raw materials – description | Share of total material cost |
|-------------------------|--|------------------------------|
| | | |
| | | |

*** Manufacturing process

1. Where are the production sites for prefab knee braces and prefab neck braces, operated by your company located?

- Prefab hard knee braces: Location: _____ Country _____
- Prefab hard neck braces: Location: _____ Country _____

2. Can you give us an indication on the following aspects?

- Number of persons directly involved in the manufacturing process
- Volume of products (e.g. pieces / year)

| | Orthopaedic braces - overall | Prefab hard knee braces | Prefab hard neck braces |
|--|------------------------------|-------------------------|-------------------------|
| Product name | | | |
| Number of persons directly involved in the manufacturing process | | | |
| Volume of products (e.g. pieces / year) | | | |

1. The production process can be characterised, from a costing point of view, as

- a. Prefab hard knee braces
 - Mainly capital intensive
 - Mainly labour intensive
 - Both (capital and labour intensive)
- b. Prefab hard neck braces
 - Mainly capital intensive
 - Mainly labour intensive
 - Both (capital and labour intensive)

2. Production is organised as follows:

- a. Prefab hard knee braces
 - Specialised approach: focus on purchase of product components, which are assembled afterwards at one site.
 - Specialised approach: focus on a number of production components at different sites after which assembling takes place at one site
 - Integrated approach: production of complete products at one site (all production steps):
 - one product per site
 - full product range at each site
 - mix of the above options
- b. Prefab hard neck braces
 - Specialised approach: focus on purchase of product components, which are assembled afterwards at one site.

- Specialised approach: focus on a number of production components at different sites after which assembling takes place at one site
- Integrated approach: production of complete products at one site (all production steps):
- one product per site
 - full product range at each site
 - mix of the above options

3. Manufacturing equipment and machinery is:

- a. Prefab hard knee braces
- Mainly developed with internal engineering department
 - Mainly standard equipment
 - Mix of both, in a sense that standard machines are purchased, but system integration and adaptation is done internally (engineering)
 - Other, please describe if relevant
- b. Prefab hard neck braces
- Mainly developed with internal engineering department
 - Mainly standard equipment
 - Mix of both, in a sense that standard machines are purchased, but system integration and adaptation is done internally (engineering)
 - Other, please describe if relevant

I. Can you list your typical production steps, and check the relevant boxes?

- Give a short description (function addressed) of each production step.
- Indicate what manufacturing equipment (machine) is used.
- Indicate its capacity (e.g. pieces /hour).
- Check the relevant boxes (IA= In house activity; OA= Outsourced activity; LI= Labour Intensive; CI= Capital Intensive).

For prefab hard knee braces:

| | description / function | manufacturing equipment | capacity | IA | OA | LI | CI |
|---------|------------------------|-------------------------|----------|--------------------------|--------------------------|--------------------------|--------------------------|
| step 1 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 2 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 3 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 4 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 5 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 6 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 7 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 8 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 9 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 10 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

For prefab hard neck braces:

| | description / function | manufacturing equipment | capacity | IA | OA | LI | CI |
|---------|------------------------|-------------------------|----------|--------------------------|--------------------------|--------------------------|--------------------------|
| step 1 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 2 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 3 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 4 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 5 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 6 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 7 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 8 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 9 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 10 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | description / function | manufacturing equipment | capacity | IA | OA | LI | CI |
|---------|------------------------|-------------------------|----------|--------------------------|--------------------------|--------------------------|--------------------------|
| step 1 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 2 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 3 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 4 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 5 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 6 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 7 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 8 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 9 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| step 10 | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

1. What is the minimum mark-up above net manufacturing costs (direct labour + material cost) to guarantee sustainable activity for the product & development function of the company?

2. What kind of distribution channels do you use for your products in the following countries?
(independent distributors – own distribution network - ...)

- Belgium:

- Sweden:

- France:

- Netherlands:

- UK:

- Canada:

3. If you use your own distribution network could you indicate the proportion between manufacturing costs and distribution costs?

We would like to thank you for your participation.

Feedback distributors

Duiding bij de prijsstructuur voor de distributie

product: harde kniebrace / harde nekbrace
nomenclatuurnummer: 645212, 647592

firma's: Dirame, Orthomedico, Axamed, Medi, Thuasne, Otto Bock, Distrac

| aankoopprijs in EUR | kniebrace gonarthrose | | functionele kniebrace | | nekbrace | | min % | max % |
|--|-----------------------|----------|-----------------------|----------|----------|---------|-------|-------|
| | min % | max% | min % | max% | min % | max% | | |
| invoerkosten | 11,25 € | 15,75 € | 9,50 € | 13,30 € | 1,75 € | 2,45 € | 5 | 7 |
| transportkosten (naar klant) | 9,00 € | 9,00 € | 7,60 € | 7,60 € | 1,40 € | 1,40 € | 4 | 4 |
| kosten van buitenmaten | 6,75 € | 6,75 € | 5,70 € | 5,70 € | 1,05 € | 1,05 € | 3 | 3 |
| consignatie | 11,25 € | 15,75 € | 9,50 € | 13,30 € | 1,75 € | 2,45 € | 5 | 7 |
| lokale R&D kosten | 0,00 € | 0,00 € | 0,00 € | 0,00 € | 0,00 € | 0,00 € | 0 | 0 |
| totale industriële kostprijs (1) | 38,25 € | 47,25 € | 32,30 € | 39,90 € | 5,95 € | 7,35 € | 17 | 21 |
| stockkosten | 22,50 € | 22,50 € | 19,00 € | 19,00 € | 3,50 € | 3,50 € | 10 | 10 |
| lonen & lasten | 67,50 € | 67,50 € | 57,00 € | 57,00 € | 10,50 € | 10,50 € | 30 | 30 |
| algemene kosten | 36,00 € | 36,00 € | 30,40 € | 30,40 € | 5,60 € | 5,60 € | 16 | 16 |
| wetenschappelijke, technische en marketingkosten | 13,50 € | 18,00 € | 11,40 € | 15,20 € | 2,10 € | 2,80 € | 6 | 8 |
| totale kostprijs van de commercialisering (2) | 139,50 € | 144,00 € | 117,80 € | 121,60 € | 21,70 € | 22,40 € | 62 | 64 |
| financiële kosten (3) | 4,50 € | 6,75 € | 3,80 € | 5,70 € | 0,70 € | 1,05 € | 2 | 3 |
| totale kostprijs (1) + (2) + (3) | 182,25 € | 198,00 € | 153,90 € | 167,20 € | 28,35 € | 30,80 € | 81 | 88 |
| marge netto | 78,75 € | 78,75 € | 66,50 | 66,50 | 12,25 | 12,25 | 35 | 35 |
| verkoopprijs exclusief BTW | 486,00 € | 501,75 € | 410,40 € | 423,70 € | 75,60 € | 78,05 € | | |
| mark-up (gemiddeld: 2,20) | 2,16 | 2,23 | 2,16 | 2,23 | 2,16 | 2,23 | | |

Op de aankoopprijs wordt gemiddeld 19% industriële kosten genomen (gemiddelde van 17 en 21 %)

Op de aankoopprijs wordt gemiddeld 63% kosten voor commercialisering genomen (gemiddelde van 62 en 63 %)

De totale kostprijs bedraagt gemiddeld 83% (som van 2 bovenvermelde zaken)

De netto marge is gemiddeld 35% op de aankoopprijs en ongeveer 16% netto marge op de verkoopprijs

(Johnson & Johnson hadden in 2006 worldwide een netto marge van 18,86%, cfr. hun annual report)

De verkoopprijs (excl BTW) bedraagt de som van de aankoopprijs, de totale kostprijs en de bruto marge.

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