FLH105 05/04

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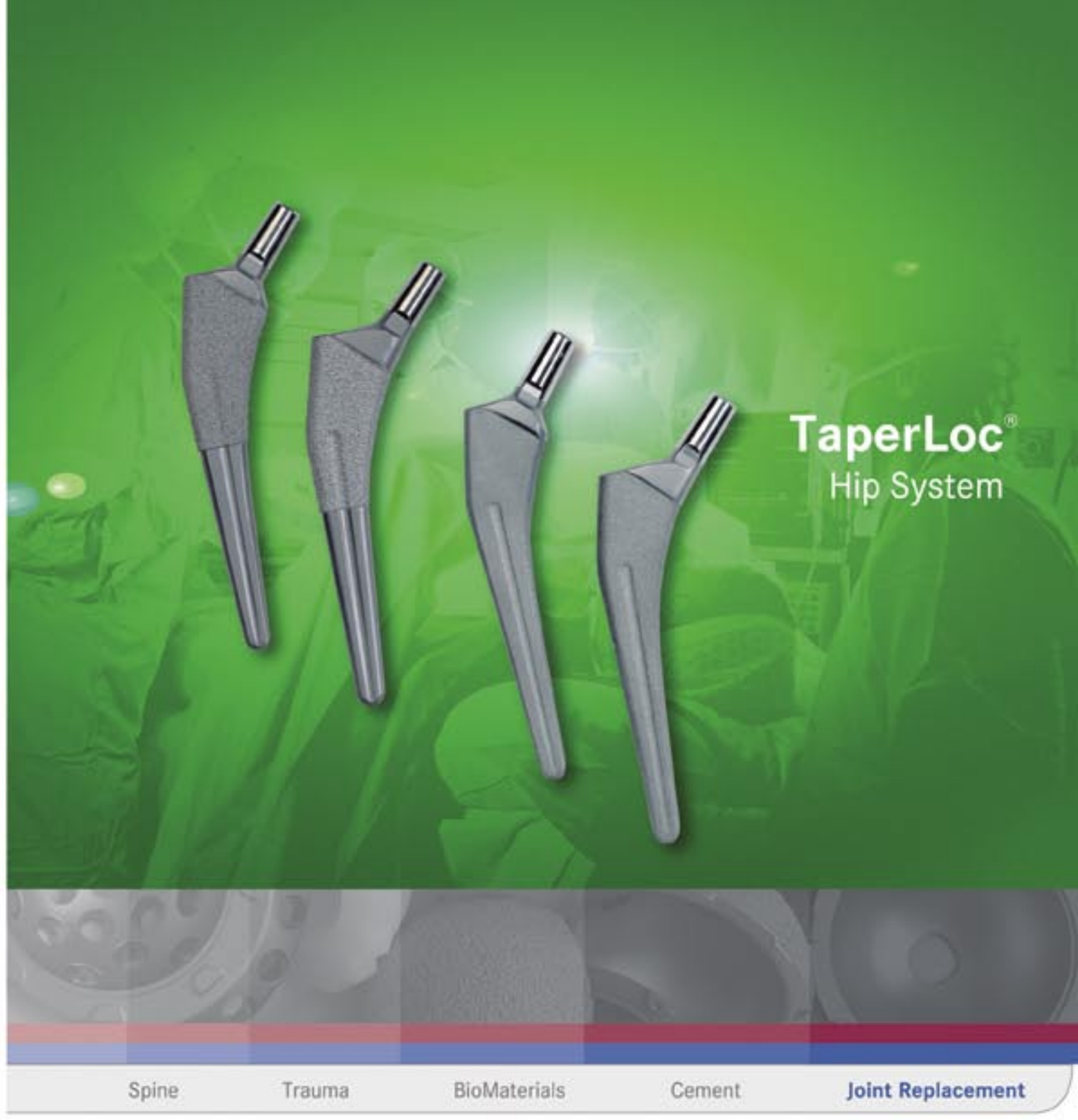


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# TaperLoc®

## Design Rationale & Surgical Technique

## Contents



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## Disclaimer

Biomet Merck Ltd, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilising the appropriate techniques for such procedure for each individual patient. Biomet Merck Ltd is not responsible for selection of the appropriate surgical technique to be utilised for and individual patient.

CE

**Long-term survivorship with less thigh pain, stress shielding and osteolysis.**

**99.6%**
**Survivorship in a series of 4,750 cases over a twelve year period.[7]**

**98%**
**Survivorship at 13 years with 100 consecutive implants and 100% follow-up. Average patient age: 37 yrs.[4]**

**0%**
**Distal Osteolysis at 8 years.[2]**

# TaperLoc®

## Total Hip System

The TaperLoc® femoral components evolved from the European philosophy of proportionately designed flat tapered stems, which have been used widely and effectively throughout Europe during the past two decades. From an engineering perspective, there are many theoretical advantages of a flat wedge-shaped collarless design, such as excellent rotational stability and load transfer to the femur. A multitude of clinical studies has concluded that these theoretical advantages do result in less pain and better durability.[1,2,4,6]

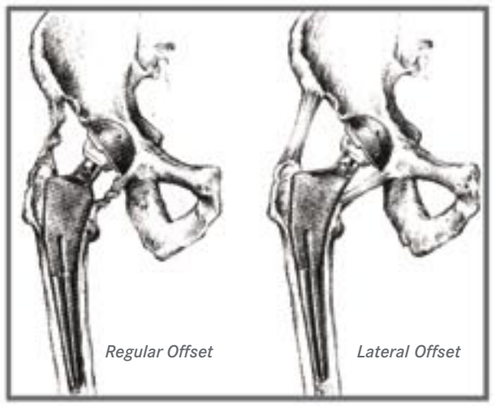


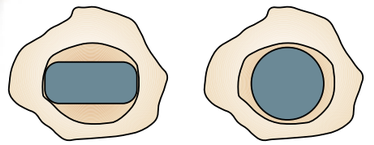

*Fig. 1*

## Offset Variations

**Introduced in 1983, the TaperLoc® hip had the first primary femoral component offered in the United States with a lateral offset option. Availability of a lateral offset design allows the surgeon to enhance stability without lengthening the leg (Figure 1). The capability of increasing the offset by 6mm helps reduce the likelihood of dislocation.**

**With most systems, lengthening the leg is the only means available to achieve this enhanced stability.**

Performance Proven



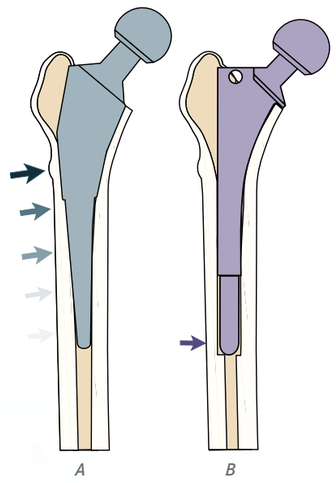
*Flat Wedge* *Cylindrical Design*

*Fig. 2*

# TaperLoc®
## Total Hip System

### Rotational Fixation

A flat wedged design used in the typical ovoid femoral canal provides better rotational stability than those femoral designs based on a round intramedullary rod (Fig. 2). It is generally accepted that rotational stability is the critical parameter for satisfactory fixation and effective pain relief. In a series of tests, Sharkey *et al.* found the TaperLoc® stem to have excellent stability with both axial and rotational loading.[6]



*A* *B*

*Fig. 3*

### Change in Stiffness

The tapered titanium geometry, inherent in the TaperLoc® stem design, allows for a gradual transition in stiffness from the upper femur, which contains the implant, to the mid femur, which is more flexible (Fig. 3a). With the use of a cobalt chrome intramedullary rod, there will be a more sudden change in stiffness from the extremely rigid upper portion of the femur containing the rod to the more distal portion (Fig. 3b). In fact, the tapered design concept has resulted in a consistently low incidence of thigh pain.[1,2,4]

### Implant Stability and Fixation

The use of a collarless design in the TaperLoc® hip tends to allow for self-seating of the implant and achievement of optimal rotational stability, immediately after implantation. The TaperLoc® collarless stem design leads to dependable fixation and an extremely low rate of revision.[3]

Simply the best

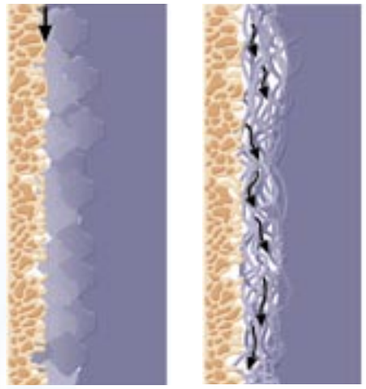


Fig. 4

## Plasma Spray Porous Coating

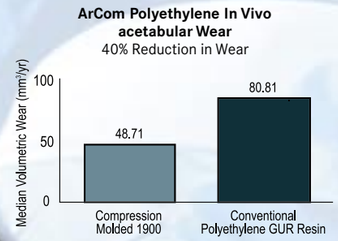
When Biomet originally considered ways to apply a porous coating on load-bearing implants, sintering of titanium alloy beads was considered but never implemented. Cobalt chrome alloy was also considered, but the greater biocompatibility and superior mechanical and material properties of titanium alloy made it the material of choice. In the early 1980's, a company founder obtained military literature, which described plasma spraying of dense titanium coatings without degradation of the substrate's fatigue strength.

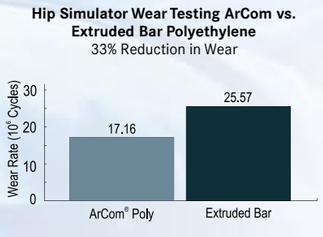
Biomet's proprietary plasma spray application is unique due to the fact that only the titanium alloy powder used to create the coating is heated, not the substrate of the implant–which can lower its mechanical properties. Randomly shaped particles tend to flatten upon impact with the substrate. This generates a random distribution of pore size between 100 and 1,000 microns providing a larger contact area between particles and substrate. Due to the larger distribution of pore size and the enhanced biocompatibility of titanium, bone can grow and mechanically anchor to the implant during all stages of the implant being accepted by the body. This is not the case for sintered beaded or fibre-mesh coatings because they have much larger pores with a very narrow distribution of pore size. The presence of a randomly distributed pore size induces higher initial fixation for Biomet's plasma sprayed implants in comparison to other coated devices.[16]

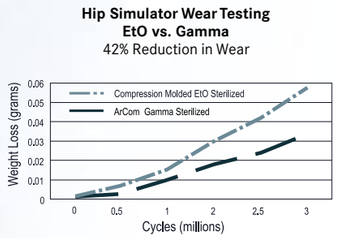
Taking into consideration the above, differences in osteolysis rates may be related to the coating configuration. The TaperLoc® stem and all of Biomet's porous coated devices employ this type of plasma spray porous coating. Plasma spray porous coating does not have connecting pores which allow the transport of fluid and debris (Figure 4). This plasma spray has demonstrated excellent clinical results since 1983 (Figure 5).

| AUTHOR | REFERENCE | HIP IMPLANT SYSTEM | YEARS FOLLOWED | OSTEOLYSIS |
|---|---|---|---|---|
| Evans and DeLee | Submitted for Publication | Bi-Metric® (Biomet) | 5 – 13 years | 0.0% |
| Mauerhan, et al. | J. Arthroplasty, 1997 | Integral® (Biomet) | 5 – 8 years | 0.0% |
| McLaughlin | JBJS | TaperLoc® (Biomet) | 8 – 12.5 years | 6.0% |
| Multi-Center Study | Biomet Clin. Report 1994 | TaperLoc® Mallory-Head® Bi-Metric,® Integral® (Biomet) | 5 years | 0.4% |
| Head, et al. | Orthopedics 1999 | Mallory-Head® (Biomet) | 11 years avg. follow-up | 0.0% |
| Rothman | Orthopedics 1994 | TaperLoc® (Biomet) | 7 years | 3.0% |
| Capello, McClain | Trans. Int'l Symp 1992 | Omnifit® (Osteonics) | 2 – 6 years | 44.7% |
| Heekin, et al. | JBJS 1993 | PCA® (Howmedica) | 5 – 7 years | 18.0% |
| Woolson, Maloney | J. Arthroplasty, 1992 | Harris/Galante™ (Zimmer) | 3.5 years avg. follow-up | 22.0% |
| Kim, et al. | Orthop. Trans, 1992–93 | PCA® (Howmedica) | 2 – 7 years | 37.0% |
| Kim, et al. | Orthop. Trans, 1992–93 | AML® (DePuy) | 2 – 7 years | 55.8% |
| Smith, Harris | CORR, 1995 | Harris/Galante™ (Zimmer) | 4.5 years avg. follow-up | 31.0% |
| Engh | Presentation, 1992 | AML® (DePuy) | 7.5 years avg. follow-up | 28.0% |

Fig. 5




## Consistent Results

Through long-term research, laboratory testing, and retrieval analysis, it has been shown that UHMWPE free of defects produces a lower wear rate than material containing defects.[12] Compression molded 1900 resin produces a UHMWPE material with very few, if any, imperfections. The superior results of this material is demonstrated by Head et al. showing a 40% reduction in wear in vivo over conventional polyethylene manufactured from GUR resin.[8] Compression molded 1900 Resin is the "gold standard" of polyethylene performance.

# *The Standard by Which All Others are Judged*

## Max-Rom®

The Max-Rom® liners are designed for patients with stable joints at trial reduction who require minimal additional stability. The Max-Rom® provides 125 degrees range of motion, the largest of any liner.

## Hi-Wall

The Hi-Wall liner offers an extended polyethylene articulating surface through an arc of 160 degrees about the liner opening to enhance hip stability.

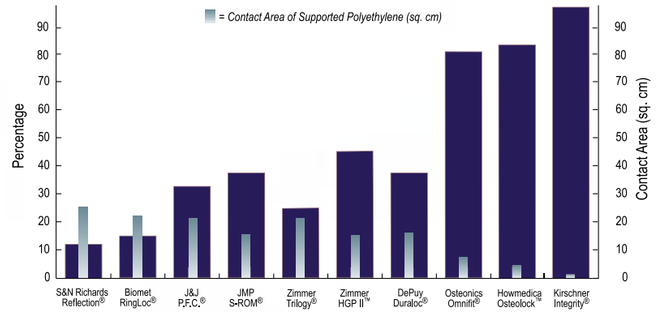
## 10-Degree

The 10-degree liner shifts the center of rotation anatomically 3.2mm to 5.8mm as the liners get larger. This liner restores the center of rotation of acetabular components which are vertically placed.

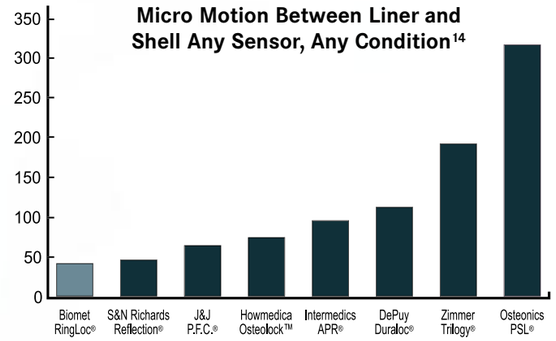
# RingLoc® Acetabular Series

**Biomet's RingLoc® acetabular components redefine the standard of acetabular technology. The components provide an unparalleled liner locking mechanism, maximum polyethylene thickness and congruity while offering the widest selection of outer shell configurations on the market. The TaperLoc® System is compatible with all RingLoc® acetabular components.**

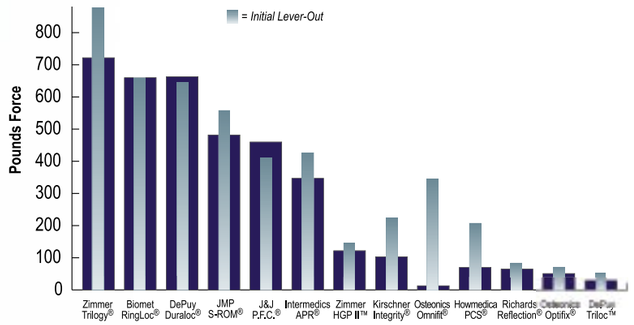
### Congruity[13]




### Micro Motion Between Liner and Shell Any Sensor, Any Condition[14]




### Liner Push-Out/Lever-Out[15]



# TaperLoc®
## Surgical Technique

Step 1.0

### Resection of the Femoral Neck

Once the hip has been dislocated, a femoral broach or femoral osteotomy guide is suggested to determine correct femoral head resection.

Step 2.0

### Opening the Femoral Canal

Once the femoral head has been resected, the femoral canal can be opened utilizing a sharp curette or starter reamer.

Step 3.0

### Broaching the Femur

Begin broaching with the smallest TaperLoc® broach. Sequentially enlarge until cortical bone contact prevents further penetration.

Step 4.0

### Trial Reduction

With the final broach in place, a trial reduction can be accomplished utilizing modular neck provisionals to ensure correct leg length and joint stability. If additional offset is required, “lateralized” head/necks may be utilized to achieve additional horizontal offset.

Step 5.0

### Cementless Stems

For cementless stems, the stem corresponding to the size of the final broach can now be implanted into the canal. If desired, an additional trial reduction can be implemented utilising provisional heads to ensure correct leg length and joint stability.

Step 5.1

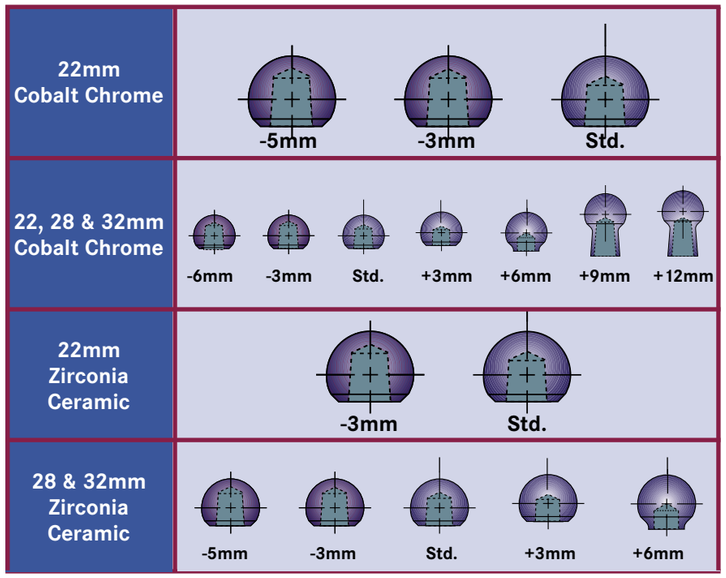
### Cemented Stems

Prior to cement and stem insertion, the femoral canal must be throughly debrided of all loose particles. This is best achieved with the use of jet pulse lavage. After debridement, the canal must be throughly dried prior to cement insertion.

The cement is inserted in accordance with the manufacturer’s recomendations. For cemented stems, the size implanted also corresponds to the final broach used. (i.e. 12.5mm broach = 12.5mm stem).

During insertion, it is recommended that the stems be inserted into the cement in a continous motion, only stopping when the stem has reached it’s final position. Pressure is then maintained upon the stem via the stem insertion instrument until the cement is fully hardened. If desired, another trial reduction can be implemented utilising provisional heads to ensure proper leg length and joint stability.

# Modular Head Options




# >98% Survivorship Rate at 10 Years[4]

- TaperLoc® Hips First 100
- Revisions 0%
- Thigh Pain 3%
- Osteolysis 3%

- 98% Survivorship at 8 to 13 years with 100 consecutive implants with 100% follow-up[4]

Average patient age: 37 years

- 99.6% survival rate at up to 12 years in a series of 4,750 cases[3]

- 94% of patients demonstrated bone ingrowth
- Average patient age: 82.3 years[7]

- At an average two-year follow-up in a matched pair analysis, no clinical data or radiographic advantage was found with the use of hydroxyapatite[5]

- Simultaneous bilateral immediate weight bearing THA with no revisions or femoral loosening[11]



## Cemented Modular Femoral Components- Biomet Type 1 Taper

| | Titanium | | Cocr | |
|---|---|---|---|---|
| Size (mm) | Standard | Lateralised | Standard | Lateralised |
| 7.5 | 164414 | 164421 | 650-0325 | 650-0331 |
| 10.0 | 164415 | 164422 | 650-0326 | 650-0332 |
| 12.5 | 164416 | 164423 | 650-0327 | 650-0333 |
| 15.0 | 164417 | 164424 | 650-0328 | 650-0334 |
| 17.5 | 164418 | 164425 | 650-0329 | 650-0335 |
| 20.0 | 164419 | 164426 | 650-0330 | 650-0336 |

## Cementless Modular Femoral Components- Biomet Type 1 Taper

| | Titanium | |
|---|---|---|
| Size (mm) | Standard | Lateralised |
| 7.5 | 164400 | 103807 |
| 9.0 | 103203 | 11-103203 |
| 10.0 | 164401 | 103808 |
| 11.0 | 103205 | 11-103205 |
| 12.5 | 164402 | 103809 |
| 13.5 | 103207 | 11-103207 |
| 15.0 | 164403 | 103810 |
| 17.5 | 164404 | 103811 |
| 20.0 | 164405 | 103812 |

## Primary Instrumentation

| Catalogue Number | Description |
|---|---|
| 31-410061 | Universal Femoral instrument tray complete with instruments |
| 31-100298 | Stem and Modular Head removal tray complete with instruments |
| 31-100683 | Modular Head instrument tray complete with instruments - Type 1 Taper |
| 31-100682 | Modular Head instrument tray complete with instruments - 12/14 Taper |
| t.b.a | Impaction Allograft tray No. 1 complete with instruments |
| t.b.a | Impaction Allograft tray No. 2 complete with instruments |

## X-Ray Templates

| | Magnification | | |
|---|---|---|---|
| Description | 110% | 115% | 120% |
| Primary Type 1 Taper Templates | 31-100710 | 31-100711 | 31-100712 |
| Primary 12/14 Taper Templates | 31-100376 | 31-100377 | 31-100378 |

## Cemented Modular Femoral Components- 12/14 Taper

| | Titanium | | Cocr | |
|---|---|---|---|---|
| Size (mm) | Standard | Lateralised | Standard | Lateralised |
| 7.5 | 650-0313 | n/a | 650-0337 | 650-0343 |
| 10.0 | 650-0314 | n/a | 650-0338 | 650-0344 |
| 12.5 | 650-0315 | n/a | 650-0339 | 650-0345 |
| 15.0 | 650-0316 | n/a | 650-0340 | 650-0346 |
| 17.5 | 650-0317 | n/a | 650-0341 | 650-0347 |
| 20.0 | 650-0318 | n/a | 650-0342 | 650-0348 |

## Cementless Modular Femoral Components- 12/14 Taper

| | Titanium | |
|---|---|---|
| Size (mm) | Standard | Lateralised |
| 7.5 | 650-0319 | 650-0349 |
| 9.0 | 650-0260 | 650-0263 |
| 10.0 | 650-0320 | 650-0350 |
| 11.0 | 650-0261 | 650-0264 |
| 12.5 | 650-0321 | 650-0351 |
| 13.5 | 650-0262 | 650-0265 |
| 15.0 | 650-0322 | 650-0352 |
| 17.5 | 650-0323 | 650-0353 |
| 20.0 | 650-0324 | 650-0354 |