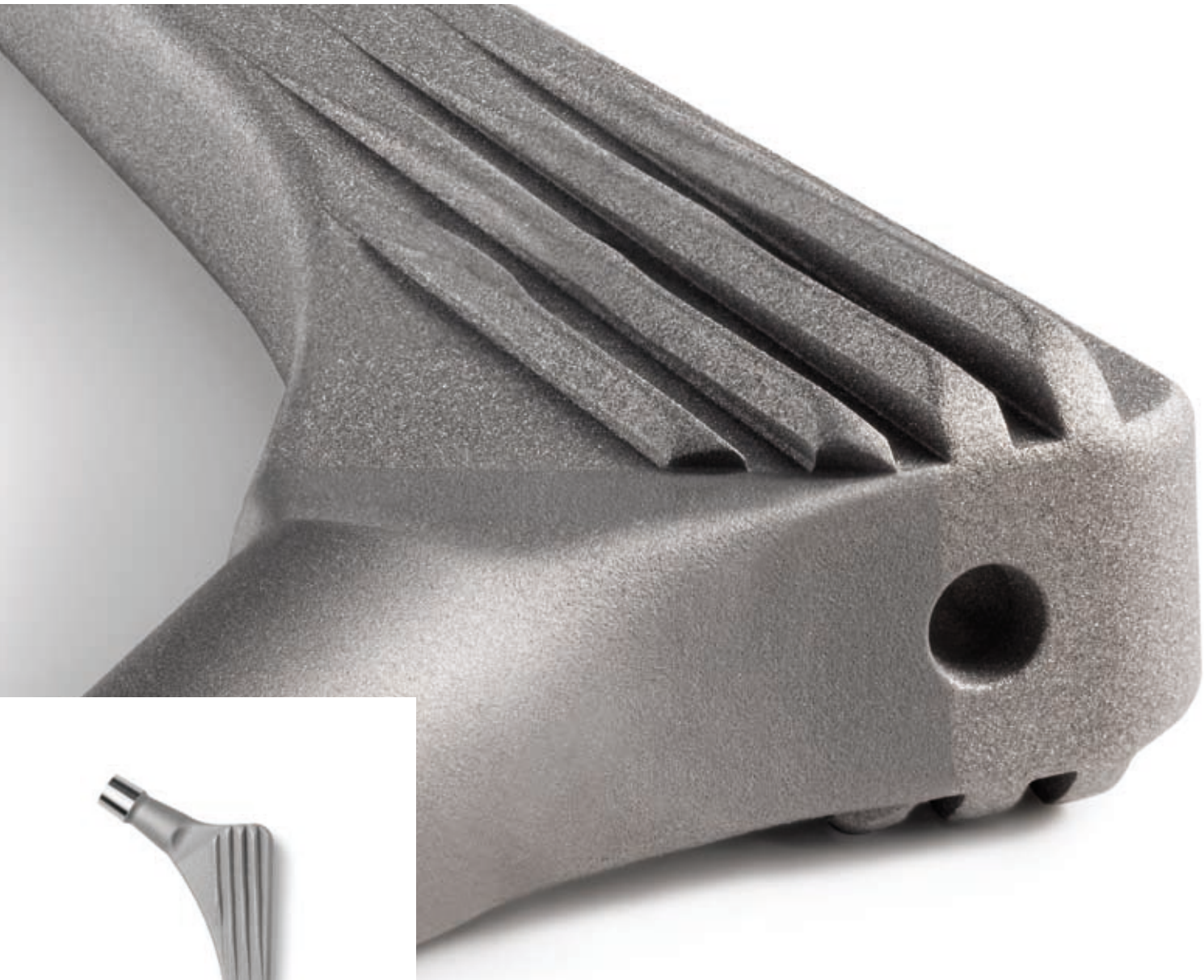
The CLS® Spotorno® Stem



Nature is Our Model

zimmer

The concept underlying the CLS Spotorno Stem is based on the idea of predominantly proximal anchorage and a long-lasting mechanical stability through osseointegration. This cementless stem, with its characteristic three-dimensional wedge shape and sharpened ribs in the proximal region, was launched in 1984. Since then, the innovative CLS Spotorno Stem has not undergone any major changes, but has enjoyed certain technical improvements brought about by experience. Over 20 years of extensively documented clinical results and over 500,000 implants (as of 2007) demonstrate the success and confirm the exceptional properties and safety of this system.

The CLS Spotorno Stem

Three-Dimensional Taper and Trapezoid Cross-Section

- Proximal transmission of the loads
- Press-fit even when subsidence is present
- Excellent primary and rotational stability

Ribs in the Proximal Region

- Large contact area for osseointegration
- Increased primary and rotational stability

Distal Reduction of the Stem

- Proximal transmission of the loads
- Rounded edges to avoid stress risers and thigh pain

Osseointegration

- Grit-blasted osteophilic titanium alloy

History
From the Idea to the Mature System

1980: The Prototype
The initial idea was to achieve proximal anchorage by means of a stem with a spinous macrostructure in the proximal region. This earned the implant the nickname of “shaved porcupine prosthesis”. This stem served as a model for the *CLS Spotorno* Stem.

1983: Creation of the CLS Stem: The Macrostructure
With the introduction of the *Protasul*®-64 titanium alloy, the stem was given a trapezoidal shape, which implements the theoretical prerequisites for press-fit in practice. The proximal design, made up of ribs running longitudinally, has been designed to optimize the transmission of loads and to increase the bone-prosthesis contact in the proximal region.

1984: Official Introduction onto the Market

1992: Changes to the Rib Structure
The new rib structure with proximally sharpened edges makes it easier for the stem to penetrate into the bone and lowers the risk of fissures.

1983

1992

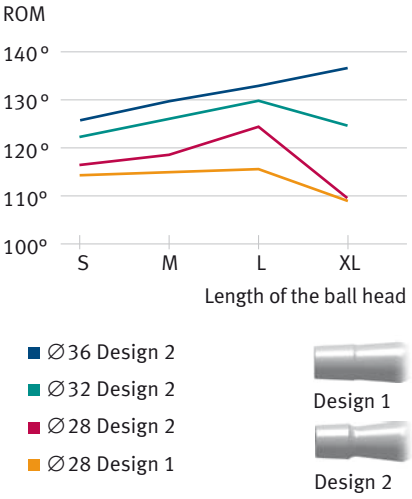
1997–2004: Range of Indications Expanded

Alongside the traditional *CLS Spotorno* Stem design with a CCD angle of 145°, a version of the stem with an angle of 135° was introduced in 1997. In order to enlarge the range of indications and to better restore the human anatomy, the CLS 125° was introduced as a second offset version in 2004. These versions present a greater offset between the axis and the center of the head, and they differ from the traditional version only because of the reduced CCD angle and because the center of the head is shifted in the distal direction.

2004: Slim Neck and Short Taper for a Better Range of Motion

In order to increase the range of motion and reduce impingement, the length of the taper has been shortened and the neck diameter has been reduced. A computerized analysis showed an average increase in range of motion of at least 5 degrees for different head diameters and neck lengths.

Modified Neck Geometry Improves ROM



Improvements in ROM with different neck diameter and taper designs with ball heads of various diameters and lengths.

Design Concept
Primary Stability for Stable Secondary Anchorage

Three-Dimensionally Tapered Structure

The *CLS Spotorno* Stem achieves primary stability through the press-fit principle. With its three-dimensional taper, the stem is forced (pressed) into the slightly undersized visco-elastic seat (fit) prepared in the cortico-cancellous bone of the metaphysis. The remodeling of the bone around the prosthesis shows that the tapered form promotes a predominantly proximal transfer of the forces.

Ribs in the Proximal Region

Anchoring of the stem in the proximal region favors the transfer of forces in this area. In the proximal region, the ribs are designed with sharp edges in order to make the introduction of the stem in the bone easier. The sharp edges lead to an increased gap between the ribs and offer the following advantages:

- Promotion of cancellous bone growth between the ribs
- Greater bone compression and therefore an increased stimulus for bone formation[1]

Tapered Design of the Distal Part of the Stem with Rough-blasted Surface

In order to avoid stress peaks, the edges of the distal part of the stem are rounded. The narrowing of the distal portion prevents direct contact with the cortical bone with the following positive effects:

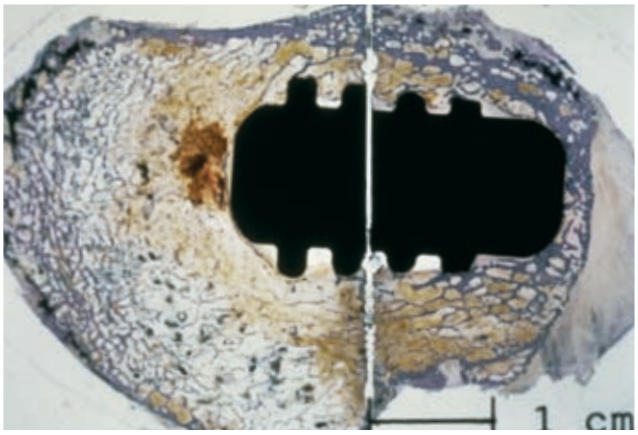
- Reduced thigh pain (absence of load-induced cortical hypertrophy)
- Potential formation of new trabecular structures on the distal surface for better osseointegration, which actually creates a functional reserve for the anchorage of the prosthesis in the bone

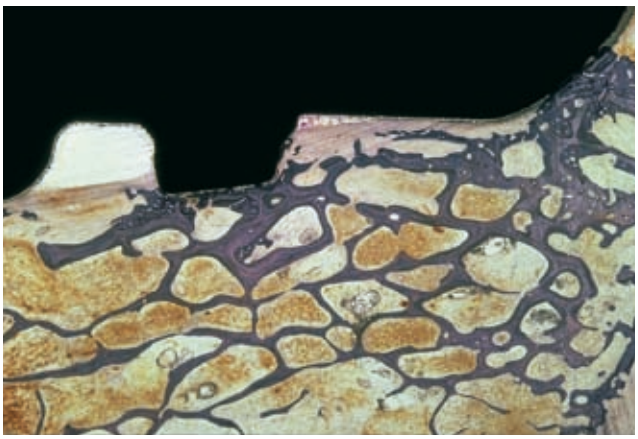
[1] L. Spotorno et al., Unsere Erfahrungen mit nichtzementierten Prothesen, Der Orthopäde (1987); 16: 225–238

The Material
Osteophilic Titanium Alloy to Promote Osseointegration

The rough-blasted *Protasul*-100 titanium alloy of the *CLS Spotorno* Prosthesis is largely osteophilic. The material and the nature of the surface play an important role in bone regeneration in the area directly surrounding the prosthesis. Generally speaking, the new bone formations accumulate preferentially on prominent parts such as the ribs or the sharp edges of the prosthesis.

The rearrangement of the trabeculae, which are subjected to a microtrauma upon surgery, is particularly rapid and takes part in the osseointegration process.





The bone parts that had initially formed have been entirely replaced by new, healthy lamellar bone.

The CLS Spotorno Stem Offset Philosophy
Optimal Reconstruction of the Anatomy

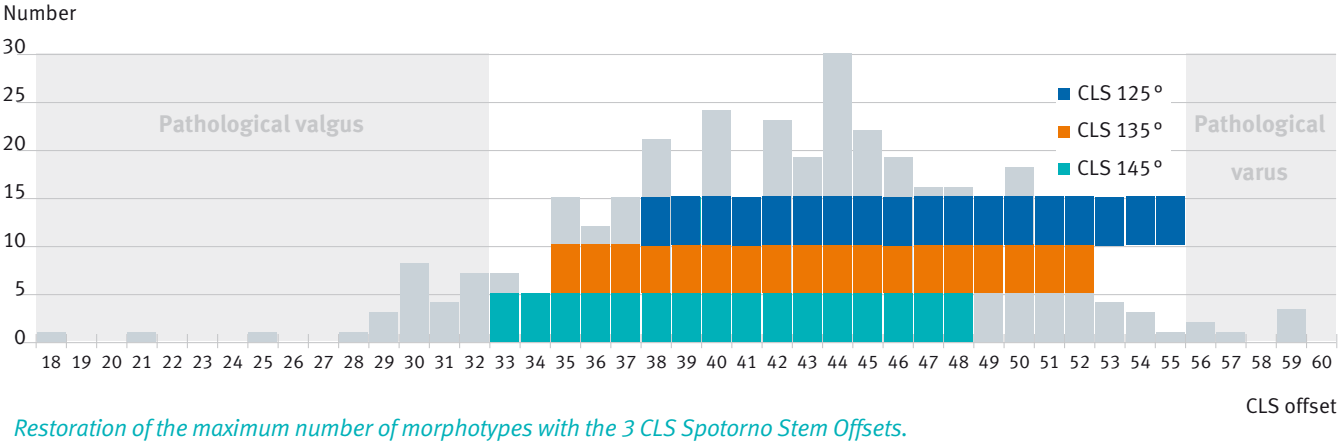
The surgeon's objective in hip reconstruction is to rebuild anatomy by restoring the optimal muscular length without modifying the length of the limb.

In an anthropometric study conducted on 353 standardized X rays in the Santa Corona hospital in Pietra Ligure, the offset and the CCD angle were measured. The offset distribution in the examined population follows a bell-shaped curve, as documented in the work of Noble[2], where the extreme values should be considered as pathological (offset values < 30 mm and > 55 mm).

Note

For all dysplastic femurs presenting an extreme valgus morphology, the use of the *Wagner Cone Prosthesis™* Stem is recommended.

Distribution of the CLS Spotorno Stem Offsets



Restoration of the maximum number of morphotypes with the 3 CLS Spotorno Stem Offsets.

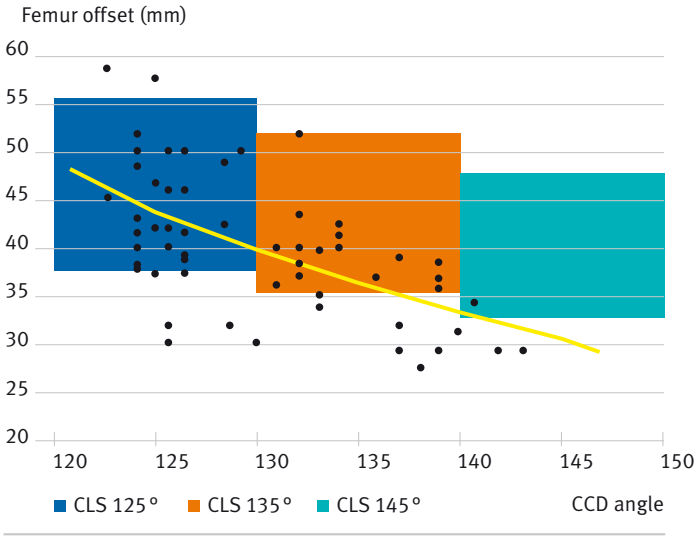
L. Spotorno and G. Grappiolo

Thanks to this unique offset concept, the CLS Spotorno Prosthesis is able to reproduce almost the entire range of physiological offsets while offering excellent control for restoring the correct leg length.

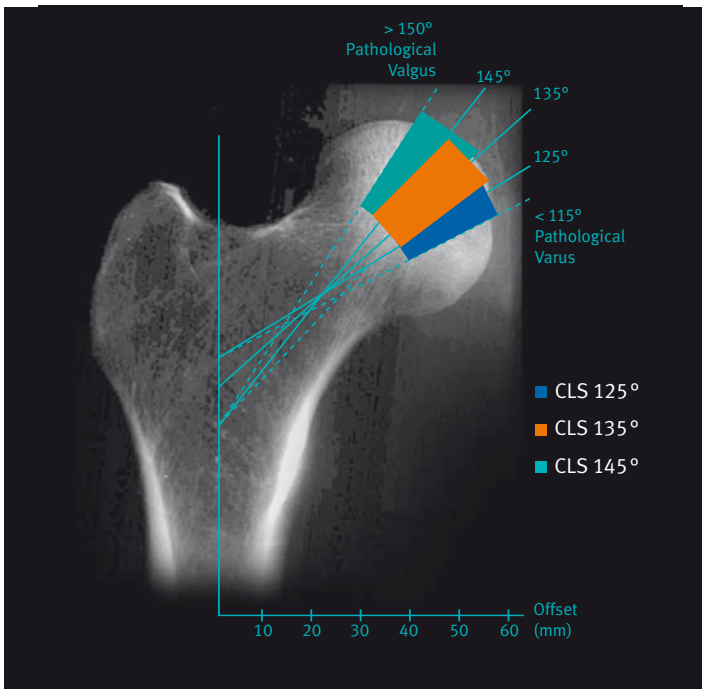
[2] Noble PC et al., The anatomic basis of femoral component design. Clin. Orthop. 1988; 235: 148–165

The study conducted in Pietra Ligure as well as the work carried out by Noble[2] on the geometry of the proximal femur describes the correlation between the CCD angle and the offset, when using the same neck length. This correlation has been taken into account in the offset concept of the *CLS Spotorno* Stem.

Ratio between Offset and CCD Angle



The three CCD angles of the *CLS Spotorno* Stem allow for a high number of morphotypes. Thanks to the tapered shape, each stem acts as a wedge, so that at least 3 different sizes of each version of the *CLS Spotorno* Stem can be inserted into the intramedullary canal. Along with the various sizes of femoral heads, it is therefore possible to offer at least 36 different offsets for the same intramedullary canal. With the *CLS Spotorno* Stem, it is also possible to rebuild the offset and the length of the limb independently, taking into account the 4 main parameters: offset, trochanteric obstruction, center of rotation and CCD angle (± varus).



Three Offset Versions
For a Wide Range of Indications

Since the CCD angle and the offset are not constant values, and these values vary greatly from one individual to another, the *CLS Spotorno* Stem now offers a wide range of offset options, to allow for an adequate restoration of biomechanical parameters like the center of rotation, the CCD angle, the leg length, and the soft-tissue balancing.

Dimensions in mm (for Head M)

Size	Length "L"	CLS 145° offset	CLS 135° offset	CLS 125° offset	Difference "a_1" 145°/135°	Difference "a_2" 135°/125°	Difference "b_1" 145°/135°	Difference "b_2" 135°/125°
5	135.6	32.8	35.1	37.5	2.3	2.4	3.6	2,5
6	139.2	33.9	36.3	38.8	2.4	2.5	3.8	2.6
7	142.8	35.0	37.6	40.1	2.6	2.5	3.8	2.8
8	146.4	36.1	38.8	41.5	2.7	2.7	4.0	3.0
9	150.0	37.2	40.1	42.8	2.9	2.7	4.1	3.1
10	153.6	38.2	41.2	44.1	3.0	2.9	4.2	3.1
11.25	158.1	39.4	42.6	45.5	3.2	2.9	4.3	3.4
12.5	162.6	40.6	43.9	47.0	3.3	3.1	4.4	3.5
13.75	167.1	41.8	45.3	48.4	3.4	3.1	4.5	3.6
15	171.6	43.0	46.6	49.9	3.6	3.3	4.6	3.7
16.25	176.1	44.2	47.9	51.3	3.7	3.4	4.9	3.8
17.5	180.6	45.4	49.2	52.8	3.8	3.6	5.0	3.9
20	189.6	47.8	51.9	55.7	4.1	3.8	5.7	4.1

Note

The same instruments and the same surgical technique are used for all *CLS Spotorno* Stems.

Clinical Results

Long-Term Clinical Results Prove the Success of this Implant

Long-term clinical studies, along with the worldwide acceptance and use of the *CLS Spotorno* Stem, are evidence of the quality of this implant. Many years of consistency in the underlying concept of the *CLS Spotorno* system have led to conclusive information based on long-term studies on the behavior of the prosthesis, its tolerability and its ability to osseointegrate.

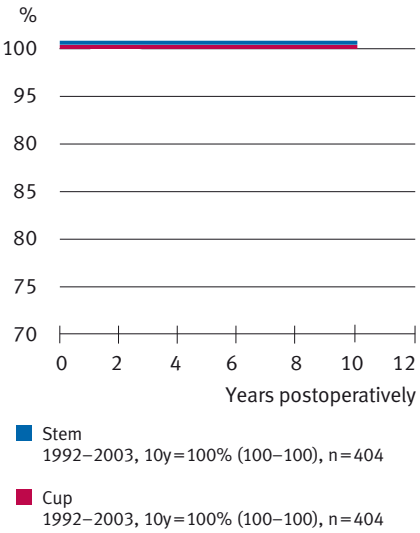
Clinical Results

Year	Author	Journal	Number of cases	Follow-up (years)	Survival rate (endpoint aseptic loosening)
1993	Bläsius et al.	Z. Orthop. (1993) 131/6: 477–616	352	4–8	98 %
1996	Bülow et al.	OP-Journal no. 2/12 (1996)	first 207	7–10	97.9 %
2000	Schramm et al.	Arch. Orthop. Trauma Surg (2000) 120: 407–412	98	10	100 %
2001	Schreiner et al.	Arch. Orthop. Trauma Surg (2001) 121: 321–324	335	8.9	98.2 %
2003	Aldinger et al.	Arch. Orthop. Scand. 74; 253–258, 2003	141 cons.	10–15	98 %
2004	Malchau et al.	Swedish National Hip Arthroplasty Register Annual Report 2003	404	10	100 %
2004	Grappiolo G. Spotorno L.	AAOS – eighteen years follow-up of the CLS uncemented stem	300	16	98 %
2005	Aldinger et al.	Akt. Traumatol. 35; 320–327	254	15–20	94 %

The *CLS Spotorno* Stem is the only uncemented stem to have 100 % survivorship at 10 years in the Swedish National Hip Arthroplasty Register 2003. This, along with all the other clinical publications, clearly proves that the original *CLS Spotorno* Stem is a cut above its competitors.

CLS Spotorno

Implant survival (with end point aseptic loosening)



The Rasp and Trial Necks
Targeted Compression and Cutting and Exact Trial Reposition

The modular *CLS Spotorno* Rasp is a high-precision instrument used for preparing an ideal seat in which to anchor the stem. It was designed taking into account both the antecurvature and the varus shape of the femur. Bone substance is removed only when it is absolutely necessary, and compressed in the remaining areas where the primary stability needs to be increased. The *CLS Spotorno* Rasp offers the optimum compromise between minimum removal of bone substance and maximum compression.

The modularity of the instruments and the trial necks facilitates intraoperative handling as well as an accurate repositioning of the trial.

The Required Result in Each Zone

Zone 1 The proximal part of the rasp has cutting edges for a length of 20 mm on the medial and lateral sides. Thus the cancellous bone on the anterior and posterior sides is only compressed, while being simultaneously prepared for the penetration of the sharp stem ribs.

Zone 2 The metaphyseal part of the rasp has cutting edges on all sides because in this zone the rasp body can come into contact with cortical bone due to the antecurvature of the femur.

Zone 3 More distally, the morphology of the femur changes from oval to a round cross-section. Here, the cutting edges of the rasp affect mainly the sharp edges.

Zone 4 Contact with the bone is avoided thanks to distal oversizing of the rasp.

MIS
A Clinically Proven Implant Combined with Innovation

Specialized instruments combined with state-of-the-art training available through the Zimmer Institute give surgeons the option to implant the *CLS Spotorno* Stem using a minimally invasive hip surgery, the *Zimmer® Minimally Invasive Solutions™ (MIS™)*.

Case Studies

The Three CCD Angles of the CLS Spotorno Stem Accomodate a Broad Range of Morphologies

Case study 1: *CLS Spotorno* Stem 145 °
with *CLS Spotorno* Expansion Cup

Preoperative

Postoperative
14.8 years

Case study 2: *CLS Spotorno* Stem 135°
with *CLS Spotorno* Expansion Cup

Preoperative

Postoperative
6 years

Case study 3: *CLS Spotorno* Stem 125°
with *Durom*® Acetabular Component and
Metasul® *LDH*™ Head

Preoperative

Postoperative

Case study 4: *CLS Spotorno* Stem 145°
with *CLS Spotorno* Expansion Cup

Preoperative

Postoperative
20 years

Disclaimer

This document is intended exclusively for physicians and is not intended for laypersons.

Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

Information contained in this document was gathered and compiled by medical experts and qualified Zimmer personnel. The information contained herein is accurate to the best knowledge of Zimmer and of those experts and personnel involved in its compilation. However, Zimmer does not assume any liability for the accuracy, completeness or quality of the information in this document, and Zimmer is not liable for any losses, tangible or intangible, that may be caused by the use of this information.

Contact your Zimmer representative or visit us at www.zimmer.com

zimmer

Lit. No. 06.01073.012x – Ed. 11/2008 ZHUB

+H8440601073012X1/$081101K08V