**Re: DIR 28523 - 41JA letter [SEC=UNCLASSIFIED]**
[redacted] to: iris
Cc: [redacted]
22/10/2012 03:44 PM

Dear Sir or Madam,

As request, please find enclosed the completed DIR form and the relevant documents.

Should you have any further queries, please do not hesitate to contact us.

Thanks.

Best regards,

[redacted]

**ESKA Australia Pty Ltd**
Address: 72 South St. Rydalmere NSW 2116 | Tel: [redacted] | Fax: [redacted]
Email: [redacted] | Web site: www.eskaaustralia.com.au



**From:** [redacted]
**Sent:** Tuesday, October 16, 2012 2:21 PM
**To:** [redacted]
**Subject:** FW: DIR 28523 - 41JA letter [SEC=UNCLASSIFIED]

FYI
--
Regards,

[redacted]

72 South Street Rydalmere New South Wales 2116 Australia | Mob: [redacted] | [redacted]
Tel: [redacted] | Fax: [redacted] | E-mail: [redacted]
| Web site: www.eskaaustralia.com.au

[redacted] | E-mail:
[redacted]



------ Forwarded Message
**From:** <wlmailhtml:IRIS@tga.gov.au>
**Date:** Tue, 16 Oct 2012 09:38:01 +1100
**To:** [redacted]
**Subject:** DIR 28523 - 41JA letter [SEC=UNCLASSIFIED]

Medical Device Incident Report Investigation Scheme (IRIS)
Office of Product Review
Therapeutic Goods Administration (TGA)
**Email:** wlmailhtml:iris@tga.gov.au <mailto:iris@tga.gov.au>
**Fax:** 02 6232 1713
**Post:** PO Box 100, Woden, ACT 2606
**Courier:** 136 Narrabundah Lane, Symonston, ACT 2609

*To ensure you are receiving all your correspondence, please update your contact details with the IRIS team. **Please note:** Only employees in your company who are listed on the ebs can be contacted about incident reports.

**Online reporting ~**
**Sponsors / Manufacturers:** http://www.tga.gov.au/safety/problem-device-report-industry.htm < http://www.tga.gov.au/safety/problem-device-report-industry.htm> *(Initial reports only)*
**Medical Device Users:** http://www.tga.gov.au/safety/problem-device-report-user.htm <

http://www.tga.gov.au/safety/problem-device-report-user.htm>



------ End of Forwarded Message

Best regards,

[redacted]

**ESKA Australia Pty Ltd**
Address: 72 South St. Rydalmere NSW 2116 | Tel: [redacted] | Fax: [redacted]
Email: [redacted] | Web site: www.eskaaustralia.com.au



hp_scan_2210201214250700.pdf Ceramic options for Total Hip & Resurfacing.pdf

Clinical_assessment_Bionik System.pdfSummary of wear tests pairing CeraMetal_ESKA-Ceram.pdf

Surgical Technique-BS Resurfacing.pdf

- MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME -
INITIAL REQUEST OF INFORMATION FROM LISTED SPONSOR

**INITIAL REQUEST FOR INFORMATION FROM LISTED SPONSOR** **Date:** 26/09/2012

DIR: 28523 Manufacturer Name: Eska Implants GmbH and Co [45325]

| Question/Requirement | | | YES | NO |
|---|---|---|---|---|
| 1) Please confirm the device's Australian Register of Therapeutic Goods (ARTG) number | ARTG: 118430 | | | |
| 2) Do you currently supply or have you previously supplied this product, with the indicated Model/Serial/Batch/Lot numbers: | | | | |
| a) To the Australian Market | | | X | |
| b) For Export | | | | X |
| 3) How many of this model have been supplied | In Australia: | 12 | | |
| | Worldwide: | N/A | | |
| 4) How many of this batch (if applicable) have been supplied: | In Australia: | N/A | | |
| | Worldwide: | N/A | | |
| 5) Are you aware of this problem, as reported? | | | | X |
| 6) If deemed necessary, is a sample of the mentioned device available for review and/or testing? | | | | X |
| 7) Have you had any other reports of similar problems with this product? | | | | X |

If **YES**, how many:

If **YES**, please give details:

**8)** If you are not the manufacturer, has the manufacturer been contacted for any other reports of similar problems with this product? ☐ ☒

If **YES**, how many:

If **YES**, please give details:

**9)** Please provide details of any action you have taken, or intend to take, regarding this problem

Product is no longer available in Australia

**10)** Please provide details of the manufacturer's investigation to date, including expected **Manufacturer's investigation completion date**

**Date:**

N/A

**11)** When returning this response to the office of the Therapeutic Goods Administration, you are requested to attach the following (if ticked):

- ☐ Sample of the product/device
- ☐ Product Specifications
- ☑ Descriptive product promotional documentation
- ☐ Instructions for use, as supplied with the device
- ☐ Device Packaging with printed instructions
- ☑ Operator's manual
- ☐ Technical Service Manual
- ☐ Clinical training manual in printed or video form
- ☐ In-house training documentation
- ☐ Evidence of compliance with the Essential Principles
- ☑ A summary of risk assessment activities performed by the manufacturer for the device, eg Risk Management Report required by Clause 8 of ISO 14971:200

**12)** Additional Information required:

| |
|---|
| |

**13)** If your device is an implantable pacemaker/defibrillator you are asked to provide the following additional information:

1. Both published and unpublished clinical trial data where events of this type are analysed.
2. The number of reported events of ALL types (including unconfirmed events), the number of devices sold and the cumulative implant months for each device in this product family.

**Information Supplied By:**

**14)** Name [redacted] Phone [redacted]

Signature [redacted] Fax [redacted]

Position [redacted] Email [redacted]

**This questionnaire and any appended documents should be returned to the TGA within 10 working days.**

Attach your completed form to an **email** and send to: iris@tga.gov.au

**Fax** your completed form to: (02) 6203 1713

*Supporting documentation following by normal mail*
*Please do not send more than one copy of your response to the TGA*

**Postal Address:** Medical Device Incident Report Investigation Scheme, Office of Product Review - Devices, Therapeutic Goods Administration, **PO Box 100**, WODEN ACT 2606, Australia

**Courier Address:** Medical Device Incident Report Investigation Scheme, Office of Product Review - Devices, Therapeutic Goods Administration, 136 Narrabundah Lane, SYMONSTON ACT 2606, Australia

Sponsors of products listed or registered on the Australian Register of Therapeutic Goods (ARTG) are reminded of their responsibilities under Section 31 and/or 41JA (as appropriate) of the Therapeutic Goods Act of 1989, to provide information relating to their product's formulation, composition, design specification, quality, method and place of manufacture, presentation, safety and efficacy, conformity to advertising regulations under the Act, regulatory history in another country, or any other matter prescribed

DIR 28523 - ARTG # 118430 - Prosthesis, internal, joint, hip, resurfacing

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:
13/09/2012

ARTG #:
118430

Brand Name:
Eska resurfacing ceramic hip replacement

Device Class:
Class IIb

Model #:

Serial #:

Software Version:

Batch #:

Lot #:

Manufacturer:
Eska Implants GmbH and Co [45325]

Sponsor:
Eska Australia [45270]
72 South Street
RYDALMERE NSW 2116

Contact Name:
[redacted]

Phone: [redacted]

Email: [redacted]

Fax:

Reporter:

Confidential: Yes

Patient Outcome/Consequences:
Revision hip replacement.

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

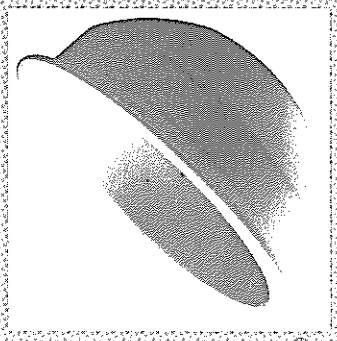
Rate of Similar Events:

Countries Similar Events Also Occurred:

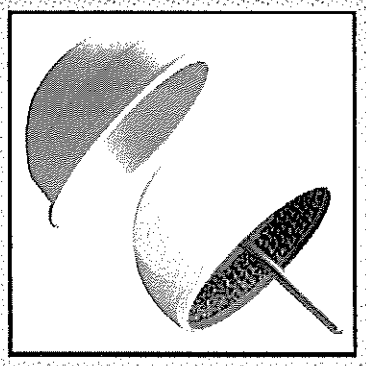
Clinical Event Information:
Delamination of the ceramic coating causing early failure requiring revision procedure.

# CERAMIC COMPOUND MATERIALS

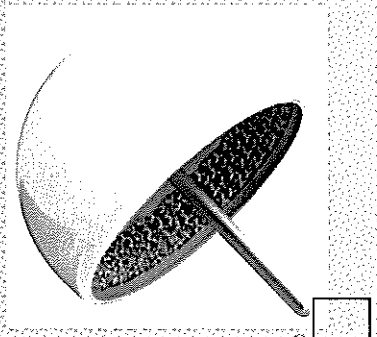
## Ceramic Options for Resurfacing & Total Hip Arthroplasty



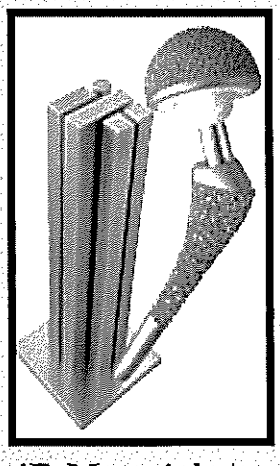
ESKA-CERAM®
Ceramic Insert



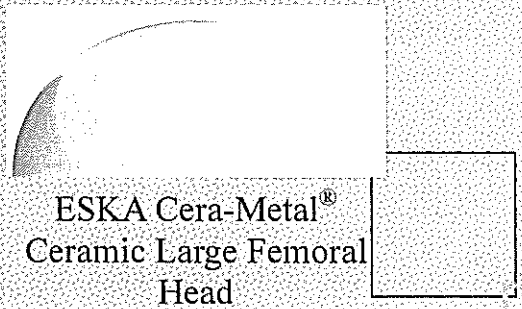
Resurfacing endoprosthesis



ESKA Cera-Metal®
Resurfacing Cemented /
Cementless options



**2006 iF Material Award**
for the **Spongiosa surface structure**

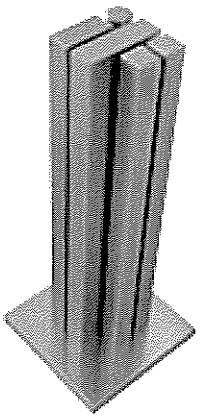


ESKA Cera-Metal®
Ceramic Large Femoral
Head

Technical Ceramic Monograph

ESKA IMPLANTS

# Historical Review



ESKA Implants GmbH & Co. KG has been awarded the iF material award at the "Hannover Exhibition 2006". [3]

Polyethylene has been used in the field of endo-prosthetics for more than 40 years. It is considered as the weakest component within existing bearing options. Mostly wear and destruction of the polyethylene bearing options due to pitting are the reason for aseptic loosening and therefore for failure of joint endoprosthesis.[1, 2, 3]

Based on numerable ring-on-disc and simulator tests a composite material has been developed for which the patent DD 272 603 A1 has been awarded and which was launched into the market as ENDOCERAM.[1]

In 1989 ESKA Implants GmbH & Co. KG reserved all rights for the production and sales of this composite material. It was modified then as a result of more scientific examinations and was named ESKA-CERAM®.[3]

After further biomechanical examinations the clinical approval for a new ESKA-CERAM® insert was achieved in 1998 by ESKA Implants GmbH & Co. KG.[3] In 2007, the ESKA-CERAM® product has been extended to a full range of Ceramic Large Femoral Heads (available for both THR and Resurfacing) and ESKA-CERAM® Inserts (available for both THR and Resurfacing).

# ESKA-CERAM®
## -- a new material in hip endoprosthesis

The composite material ENDOCERAM consists of a polyurethane matrix and of a mixed-in glass ceramic powder. By starting manufacturing at ESKA Implants GmbH & Co. KG ESKA-CERAM® for THR and Resurfacing has been modified to comprise two-thirds polyurethane and one-third $Al_2O_3$—Ceramic substituting the glass ceramic.[4]

The new material ESKA-CERAM® is a little lighter in appearance than the original material and has a porcelain-like look.[5] Its wear rates are of a similar low order of magnitude as those reported for metal-metal and ceramic-ceramic combinations. A great advantage of the material is that it permits the production of asymmetrical inserts for acetabular cups.[4]

Fig.1 ESKA Cera-Metal® Large Femoral Head (38 , 44 & 48mm)

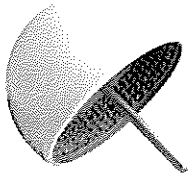


Fig.2 ESKA Cera-Metal® Resurfacing Head

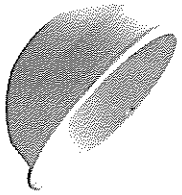
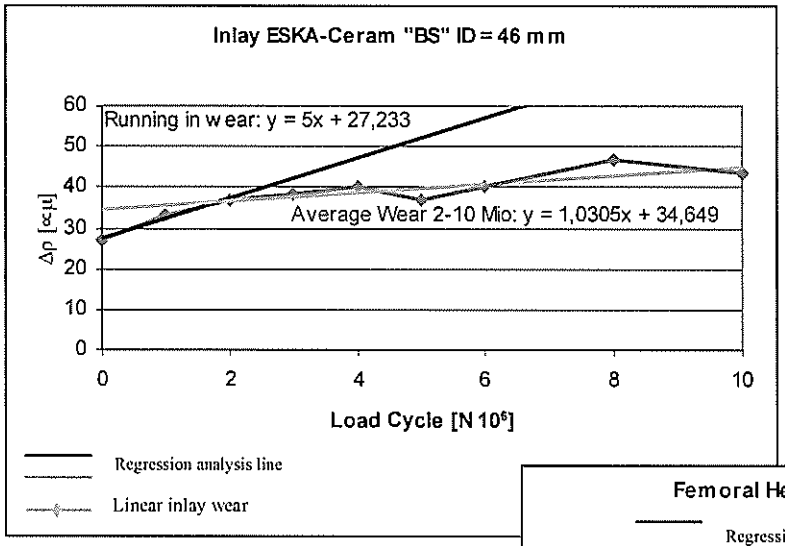


Fig.3 ESKA-CERAM® Insert (available for both THR and Resurfacing)

# Laboratory Results of 10 Mio Simulator Tests

The performance of the new material was shown in numerable tests using a load and movement simulator.[6]

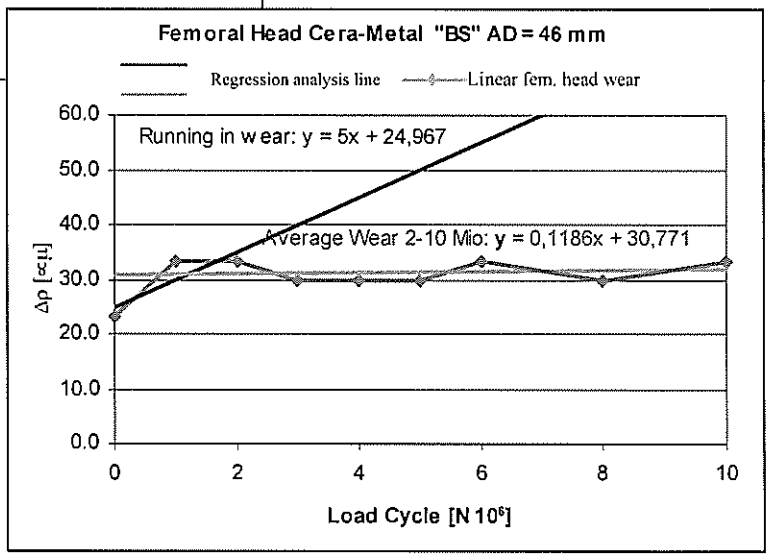



ESKALAB IMPLANTS

Fig. 5 Simulator Testing
Pairing (D = 46 mm)
Cera-Metal/ESKA-Ceram®

Linear Wear Rate: $\Delta Z = 1.2\ \mu m/10^6$

**Source:**
ESKA Lab. 23556 Lübeck, Germany




Run-In
Inlay ESKA-Ceram: 5 µm
Femoral Head Cera-Metal : 5 µm

TUHH
*Technische Universität Hamburg-Harburg*

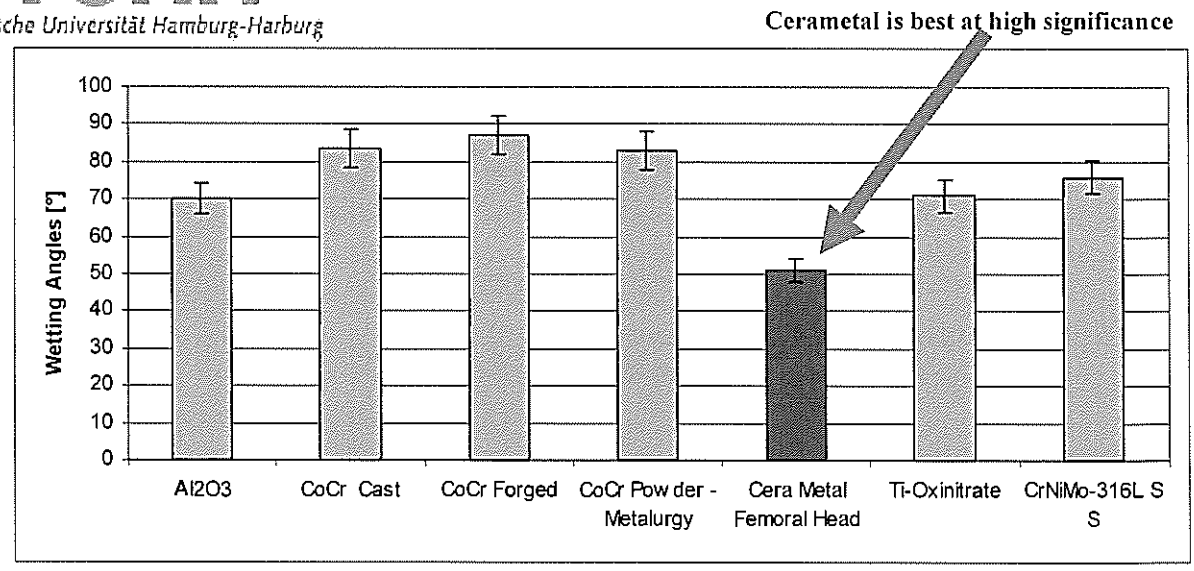



Fig. 4 Comparison of wetting angles with bovine serum (TU Hamburg)

**Source:**
TUHH, Technical Univ. Hamburg, Biomechanics Dept., 21079 Hamburg, Germany

# Laboratory Results of 10 Mio Simulator Tests

Fig. 6 Simulator Testing—Results

| Diameter | D = 46 mm | | D = 52 mm | |
|---|---|---|---|---|
| **Component** | Inlay | Cap | Inlay | Cap |
| **Run in Wear** | 5 µm | 5 µm | 26 µm | 5 µm |
| **Linear Wear Rate** | < 1 µm/$10^6$ | 1 µm/$10^6$ | 0, 9 µm/$10^6$ | 1, 8 µm/$10^6$ |
| **Wear Rate Bearing** | 1, 2 µm/$10^6$ | | 2, 7 µm/$10^6$ | |
| **Wear Rate Total** | **< 5 µm/$10^6$** | | | |

Linear Wear Rate of the Pairing Cera-Metal®/ESKA-Ceram®

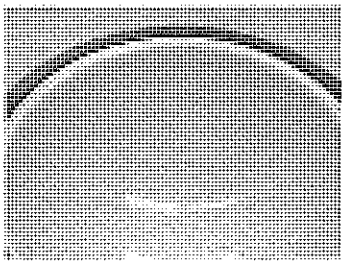


Fig. 7a Inlay 46 after 1 Mio LC (Load cycles)

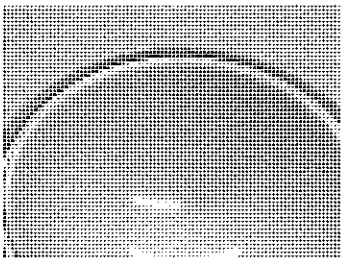


Fig. 7b Inlay 46 after 10 Mio LC (Load cycles)

ESKALAB IMPLANTS

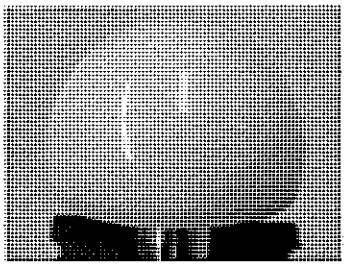


Fig. 8a Cap 46 after 1 Mio LC

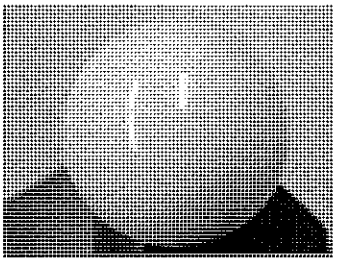


Fig. 8b Cap 46 after 10 Mio LC

**Source:**
ESKA Lab. 23556 Lübeck, Germany

# ESKA-Bionik® System — Ceramic on Ceramic

## "ESKA Cera-Metal®" Resurfacing Head (Fig. 9)

- Sizes from 38 mm to 58 mm, 2 mm increments
- 3 mm guiding nails in 30, 40, 50 mm length

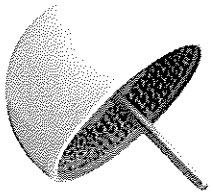


Fig. 9

## "ESKA Cera-Metal®" Large Femoral Head (Fig. 10)

- 3 head sizes in following diameters : 38, 44, and 48 mm, with Short, Medium & Long options
- Asymmetrical insert available (10° taper)

Fig. 10

# ESKA-Bionik® System —
## BS Acetabular Cup with Spongiosa Metal® surface structure

Positive results for the metal Spongiosa cups with ESKA-CERAM® inserts can be reported.[7] For an optimal outcome, ESKA Implants GmbH & Co. KG proudly provides three types of Metal Shell.

- Cementless anchorage : using surface structure Spongiosa Metal® II.
- Extensive range of sizes : Standard Shell, Screw Fixation Shell & Dysplasia.
- Various insert options : Metal-on-metal, ceramic-on-ceramic, metal-on-polyethylene as well as ceramic-on-polyethylene bearing options.
- Extensive range of sizes : available in 11 sizes (OD=46 to 66 mm, 2 mm increments).
- Material : CoCrMo TiNb-Coat.

**Metal Shell, Cem.less** Fig. 11
TiNb-COATING
Size: OD=46 to 66 mm
(HA-Coating available upon request)

Ring shaped fixation assures primary stability by initial press fit.

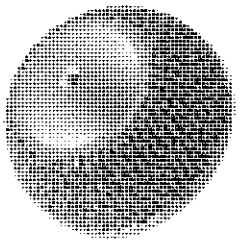


Fig. 11

**Metal Shell, Cem.less** Fig. 12
TiNb-COATING, **Screw Fixation**
Size: OD=46 to 66 mm
(HA-Coating available upon request)
(Various sizes of screws are available)

Additional screw supports primary press-fit anchorage.

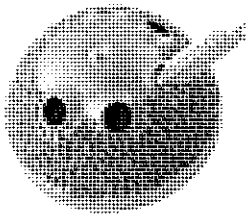


Fig. 12

**Metal Shell, Cem.less** Fig. 13
TiNb-COATING, **Dysplasia**
Size: OD=46 to 66 mm
(HA-Coating available upon request)

A combination of threaded posts and fixation provides primary stability.

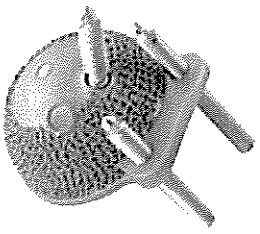


Fig. 13

# Spongiosa Metal® Porous Structure
## *Implanted since 1981*

The surface of the cementless ESKA endoprosthesis is a three-dimensional grid net structure, which is adapted to the natural spongiosa. The first clinical introduction was in 1981 of Spongiosa Metal® then Spongiosa Metal® I in 1989 followed by the current Spongiosa Metal® II in 1990.

The Spongiosa Metal® II (fig.14) structural height is adjusted between .65mm to 3mm and its porosity is between 70 - 80% .

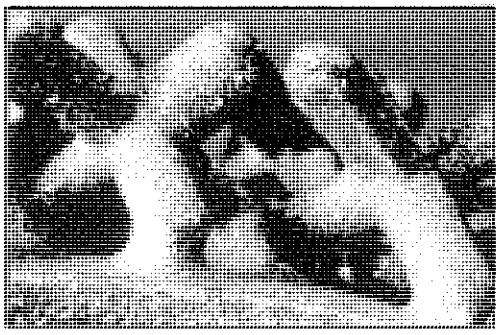


Fig. 14 Spongiosa Metal® II

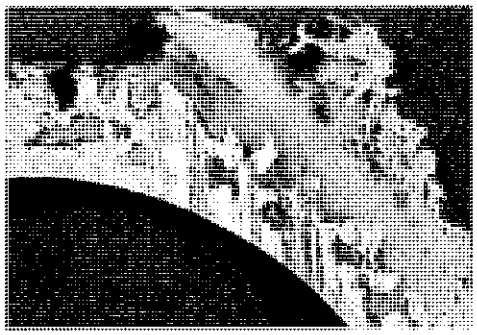
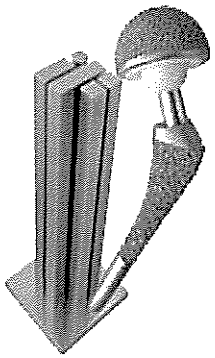


Fig. 15 Bony in growth into Spongiosa Metal®

At the "Hannover Exhibition 2006", ESKA Implants GmbH & Co. KG has been awarded the iF material award for its surface structure Spongiosa Metal® (since its introduction in the year 1953 this award is a well-known established label wherever outstanding design is involved). [8]



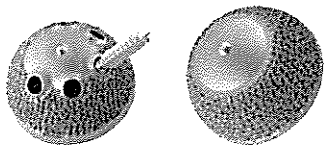
The surface structure and the implant body are cast as one piece. Therefore a homogeneous casting is accomplished. Primary stability is realized by an immediate press-fit with long term stability achieved by bony in growth (fig.15) rather than bony on-growth to a roughened surface. The three-dimensional porous structure has been in successful clinical use since 1982 [5, 8, 9, 10, 11]

References:
1. M.Blüthner, University Leipzig, Department of Orthopedics(Director. Univ.-Prof.Dr.med.G. von Salis-Soglio). "ENDOCERAM- A Possible Alternative to Polyethylene in Hip Arthroplasty"
2. Quack G et al. "Design considerations for improving the acetabular cup of the ESKA hip endoprosthesis by using the ceramic/ceramic wear couple." Biomed Tech (Berl). 1996 Sep; 41 (9): 253-9.
3. ESKA Implants GmbH & Co. KG website, http://www.eska-implants.de/cms/front_content.php?idart=133
4. Scholz, J et al "ESKA-Ceram — a new material in hip endoprosthetics" Biomed Tech (Berl). 2000 Dec; 45(12): 377-9.
5. Scholz,J et al."Twenty year follow up of the uncemented spongiosa metal surface SMS total hip artroplasty" Oral presentation German orthopedics
6. Test reports 2004 to 2007 from external and internal Biomech. Labs. ENDOLAB, 83101 Rosenheim, Germany; ESKA Lab. 23556 Lübeck, Germany; TUHH, Technical Univ. Hamburg, Biomechanics Dept., 21079 Hamburg, Germany.
7. Von Salis-Soglio G., et al. "Cementless acetabular cup with Spongiosa Metal® and surface Ceramic-Polyethylene insert (ESKA-CERAM®)" Effenberger H., Zichner L., Richolt J.A., MCU Verlag 2004, P. 147-150
8. Japan Design Net. "iF Material Award". http://global.japandesign.ne.jp/COMPE/report/ima2006/. April 2006.
9. Sielewicz,M et al. "Five year follow-up of 605 cases of the MCCL (metal cancellous cement less Lubeck) Total hip prosthesis" Orthopaedic Clinic of the Neukolin Hospital, West Berlin pg:433-443
10. Matsui, M et al. "The Metal-Cancellous Cement less Lubeck total hip arthroplasty" Journal of Bone& Joint surgery-British 1998:404-410
11. Kinner, B et al. "Hydroxyapitite-coated open Macroporous, Anatomical Hip prosthesis" Z. Orthopad. 1999; 137:114-121

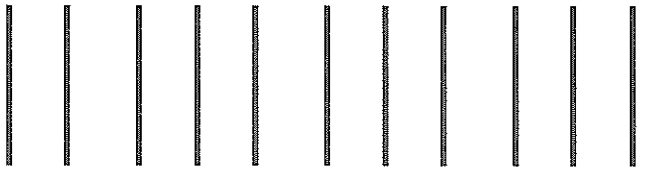
# ESKA-CERAM® BS Bionik®-System

## Hip Surface Replacement

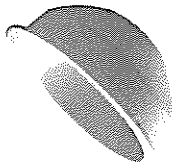
Metal Shell



46 / 48 / 50 / 52 / 54 / 56 / 58 / 60 / 62 / 64 / 66



ESKA-CERAM®
Insert for HSR



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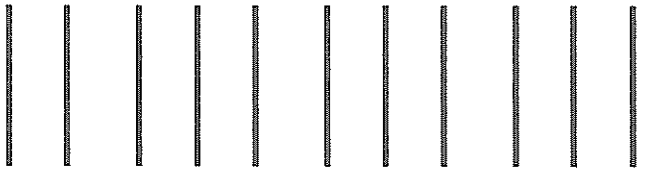
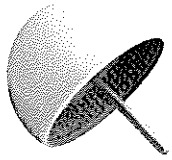


ESKA-CERAM®
Resurfacing Head



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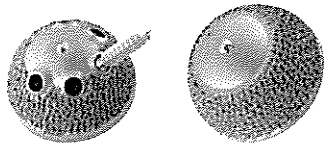
## Total Hip Replacement

Metal Shell



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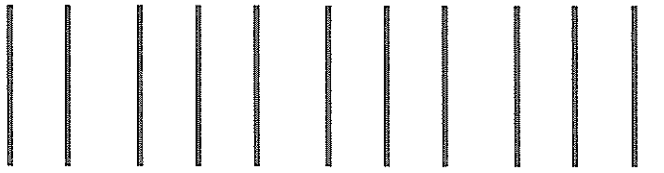
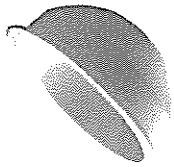


ESKA-CERAM®
Insert for THR



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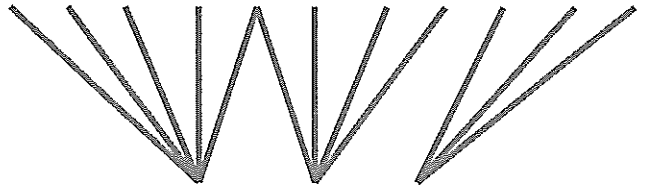
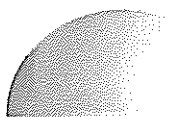


ESKA-CERAM®
Large Femoral
Head



38 / 44 / 48 mm

ESKA AUSTRALIA
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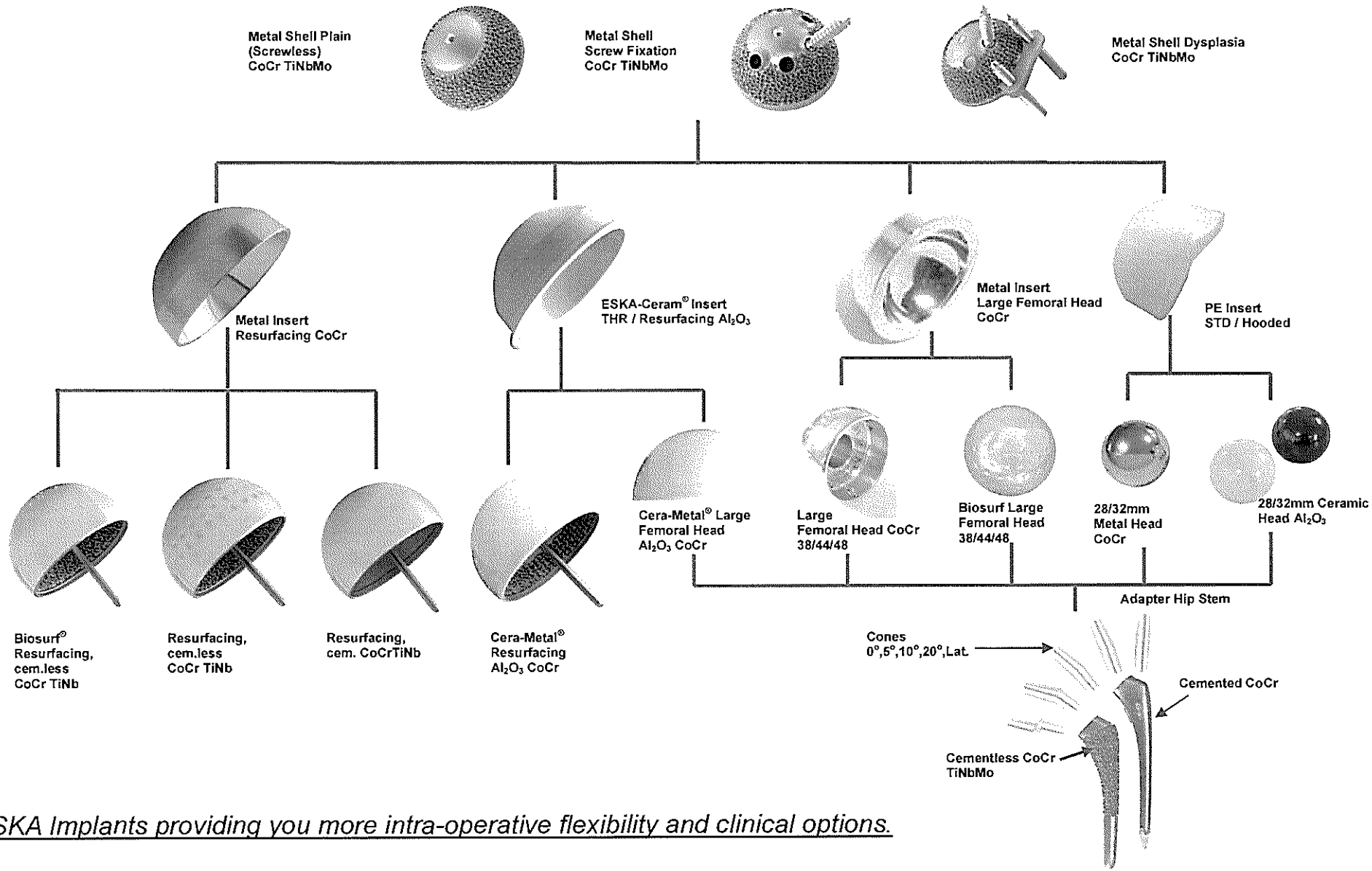
# ESKA Genius® Primary & Resurfacing Hip System Overview




*ESKA Implants providing you more intra-operative flexibility and clinical options.*

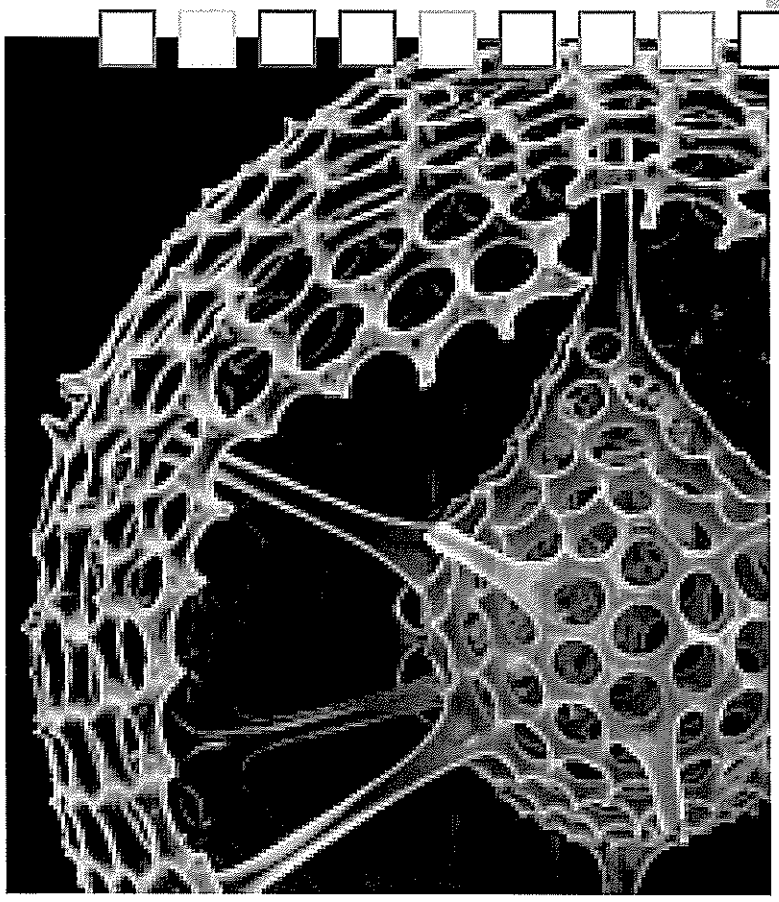
*Pages 16-30 exempt in full under section 47(1)(b) of the FOI Act*

# Surgical Technique "Nail"

## ESKA Genius® Hip-System
## Hip Resurfacing
## ESKA Bionik®-System

Type "Standard" and "Cornwall"

BIONIK®-SYSTEM

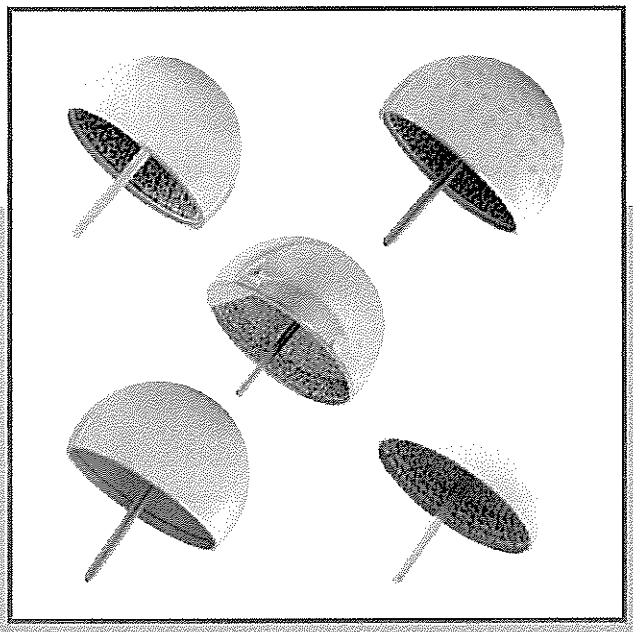


ESKA IMPLANTS

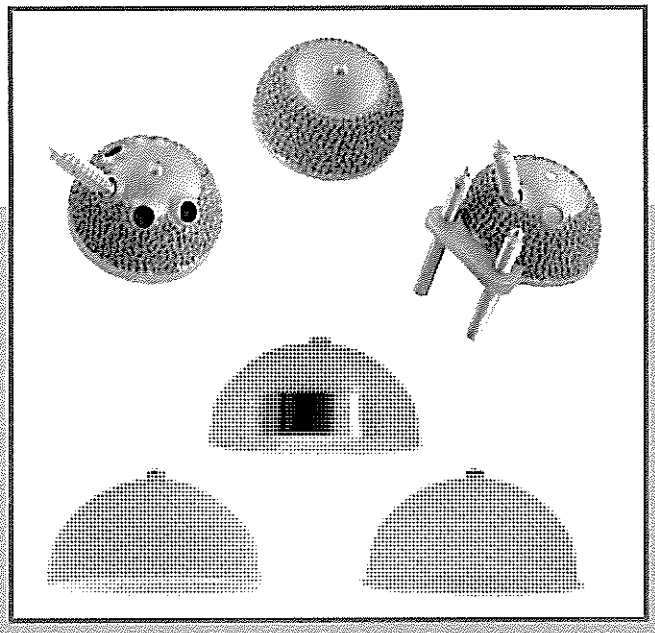
securely better

# ESKA Genius® Hip-System
# Hip Resurfacing

Today's material standards, the medical and technical know-how as well as the modern manufacturing facilities are promising high grade of quality for a reliable system of hip resurfacing. The modular concept os ESKA Implants made the Hip Resurfacing "BS" Bionik®-System inimitable.



■ The femoral part of the Bionik-System is designed modular. The central pin for the fixation of the femur can be implanted with different diameters and length.



■ Due to the modularity of the cup-system the insert can be revised without removing the metal shell from the acetabular-fixation.

The following surgical technique describes the use of the ESKA Bionik® System hip surface replacement with reference to the instruments available for this procedure.

## Contents

## 1. Preoperative planning

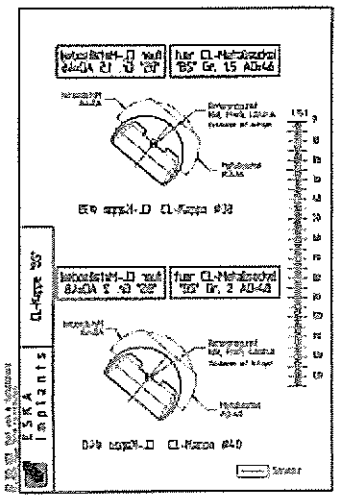
With the help of preoperative planning the following aspects should be specified before the surgery starts:

- Size of implants
- Varus / valgus
- Anteversion, retroversion
- Pathological situation of femoral head

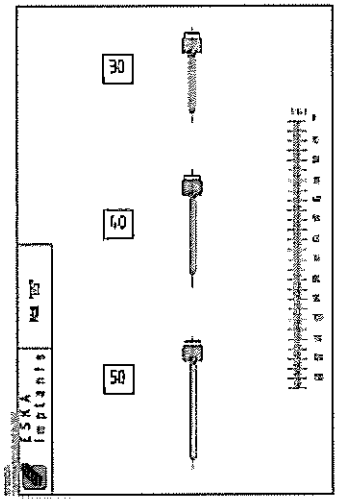
Appropriate planning templates are available for this purpose **(Fig. 1)**. When using x-ray templates note that the image scale of the femur changes depending on the distance between the x-ray source and film and patient and film. A default magnification factor of 15% is used with the templates for the hip surface replacement. Corresponding to the average magnification factor in most clinical x-ray images. Where taller or obese patients are involved a higher magnification factor can be used, because the distance of bone to film is longer. A mark can be set at the height of the femur for measurement on the x-ray image to define the magnification of the x-ray image.

⚠ *Note: X-tray templates with a different magnification scale are available on request.*

It is important for the final result to determine the exact position of the resurfacing. The pathological situation of the femoral head can be identified and the natural position of the centre of rotation can be reconstructed with reference to the femoral neck from the x-ray images. A frontal view (A/P) and a side view (M/L) are required both. The x-ray template is positioned to size the implant. The system can also be supported by electronic planning systems. For more information please contact ESKA Implants.



Resurfacing, modular with CL metal shell, cementless




Nail

Fig. 1 X-tray template

# 2. Surgical technique

## 2.1 Approach

The surgeon is responsible for selecting the approach for this type of implant. Following standard criteria are significant: complete uncovery of the acetabulum and proximal femur is required to allow accurate preparation of these areas without affecting the positioning of the components.

## 2.2 Determining the size of the resurfacing

The size of resurfacing selected during preoperative preparation is verified during the procedure. The size of the femoral neck is measured with the gauge **(Fig. 2)**. The size of the femoral neck measured in a/p-direction (longitudinal oval) determines a minimum resurfacing size, and a smaller size must not be used.

⚠ A too small selected implant could damage important blood vessels and cause premature loosening of the resurfacing.

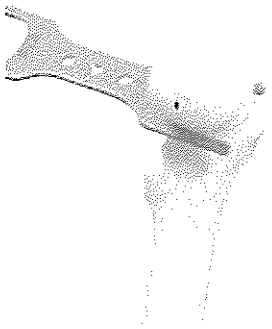


Fig. 2

## 2.3 Preparation of the femoral head

### 2.3.1 Determining the point of entry (centre of femoral neck)

The entry point on the femoral head can be marked by positioning two gauges with rods placed with 90° inbetween (crosshairs) **(Fig. 3a, b)**.

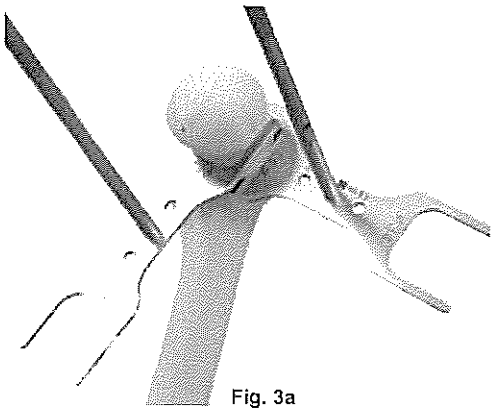


Fig. 3a

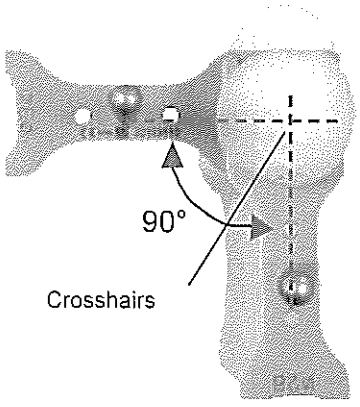



Fig. 3b

The hole for the central guiding pin is drilled into the femoral neck using the drill guide.The twist drill (D=2.5 mm) is inserted through the feed hole of the drill guide **(Fig. 4)**. The drill must aim towards the head center.

Fig. 4

Following the drill is aligned to the head and the drill guide is pressed onto the femoral head, taking into account the varus, valgus and ante-version and retroversion situation of the femoral neck. Two pins on the bottom of the drill guide secure the position. Then the pilot hole is positioned **(Fig. 5)**.

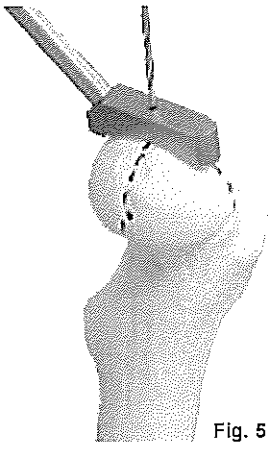


Fig. 5

Now the central position of the direction of the drill hole is checked with an image intensifier. A short position tack is placed as an indicator. The position is checked with the image intensifier **(Fig. 6a, b)**.

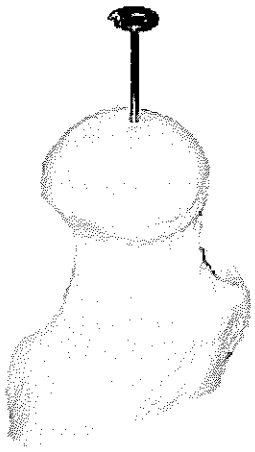


Fig. 6a

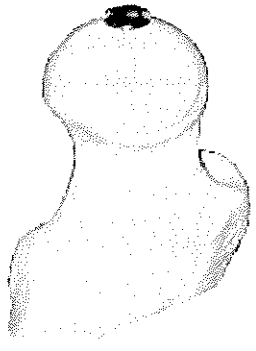


Fig. 6b

If the positioning tack is not central to the head, the offset can be corrected with the head paralleler **(Fig. 6f)**.

The positioining tack must be removed and the guide pin of the head paralleler is positioned in the pilot hole **(Fig. 6c, 6d)**. A new hole is drilled in the femoral head to take the required offset into account with the twist drill D=2.5 mm **(Fig. 6e)**.

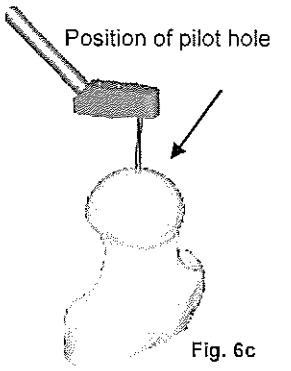


Fig. 6c

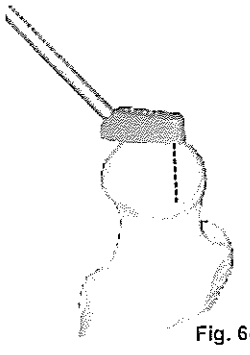


Fig. 6d

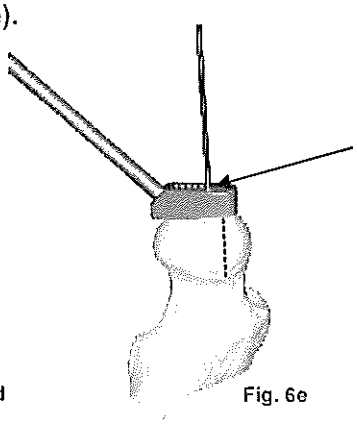


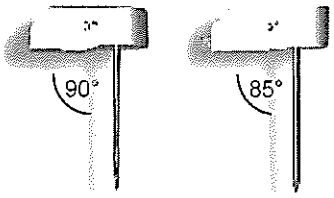
Fig. 6e


Fig. 6f Head paralleler view from above

The position can be checked again with the positioning tack and the image intensifier. The correction procedure can be repeated until the correct position is achieved. A pin is inserted tightly into the correct hole.

A second paralleler with a 5° inclination is available for angular correction **(Fig. 7)**.

Fig. 7



Standard 0° angular correction 5°

The guide pin is inserted to the stop into the femoral neck at the definitive hole position. The guide pin is inserted with the handle attached **(Fig. 8, 9)**. Afterwards the handle is removed.

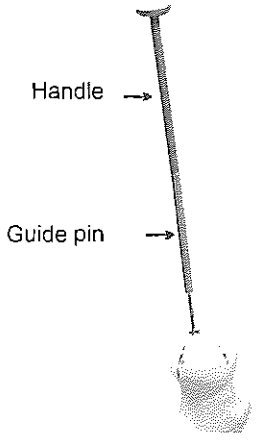


Fig. 8

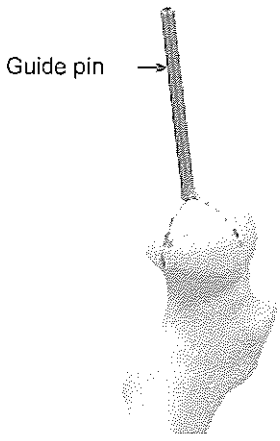


Fig. 9

### 2.3.2 Preliminary preparation of the femoral head

Stepwise preparation is carried out, starting with the largest resurfacing reamer. Preparation is continued with smaller sizes until a size is reached that is two sizes larger than the planned implant size.
The resurfacing reamers are positioned through the guide wire inserted in the femoral head **(Fig. 10a - c)**. The guide pin must be removed after preliminary preparation.

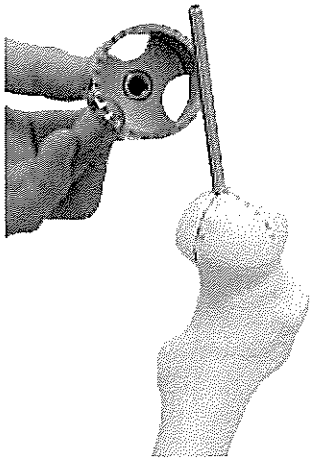


Fig. 10a

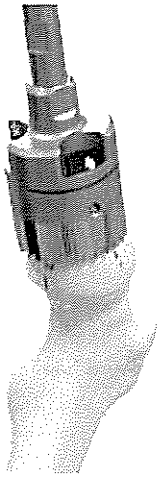


Fig. 10b

Fig. 10c

## 2.4 Preparing the acetabulum

Mainly the preparation of the acetabulum is to be done as usual. The only important thing to beware of is that the ESKA Metal Shell Bionik®-System is different to standard systems with the Spongiosa-Metal® Structure II surface. This allows highly primary stability caused by press- and friction fit and a good long-term stability caused by osseous integration. Therefore a fixation in the cancellous bone is necessary. The first step is to remove the osteophytes and the soft tissue of the acetabular rim.

⚠ *Note:*
The size of the resurfacing has been determined during preoperative planning and as a result the size of the metal shell has been defined with reference to the insert. The primary stability of the metal shell cementless is achieved by press-fit anchorage, which requires the final implant to be 2 mm larger than the reamer used last.

**The largest possible metal shell should be selected (see table p. 19)**

*1. Femoral Hip Resurfacing Nail® Implant + 6 mm = Acetabulum Reamer*
*2. Acetabulum Reamer + 2 mm = Size of Metal Shell "BS"*

Example:

- *Hip Resurfacing Nail® Implant = 50 mm*
- *Acetabulum Reamer = 56 mm*
- *Acetabulum Implant Metal Shell "BS" = 58 mm*

### 2.4.1 Reaming the acetabulum

In the first step the cranial region of the lunate surface of the acetabulum is hollowed out with the curved gouge chisel (**Fig. 11**).

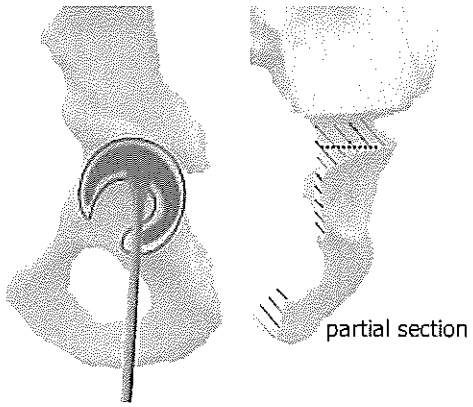



**Fig. 11** Preparing the cranial region of the lunate surface

⚠ The compatibility to the available power tools are to be considered. ESKA Implants offers a wide range of power tool connectors upon request.

The Acetabulum is incrementaly prepared up to the required size and until the subchondrale bleeding becomes visible (**Fig. 12**). This way the bony integration of the metal shell is guaranteed. During reaming it is to beware of reaming into cranial direction.

⚠ *The reamer must be prevented from migrating in a caudal direction (**Fig. 12**).*

The desired positioning (inclination 35°- 45° and anteversion 10°-15°)[1)] must be taken into account. The reaming depth is defined with the edge of the blade at least 3 mm below the margin of the acetabulum. This guarantees an optimum press-fit seating of the implant in the acetabulum (**Fig. 12a**).

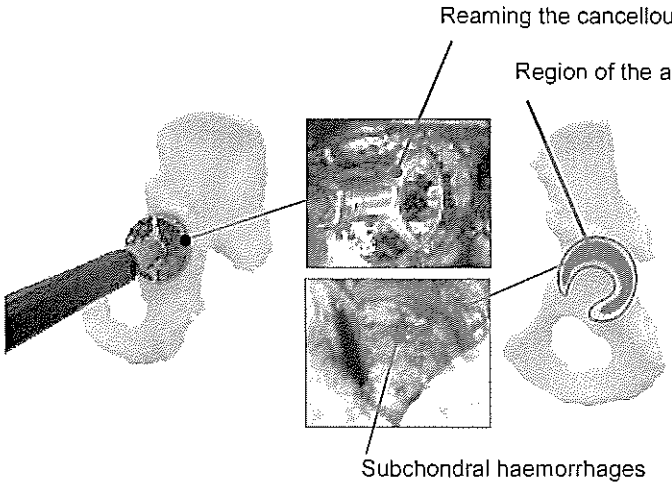



**Abb. 12** Reaming the acetabulum

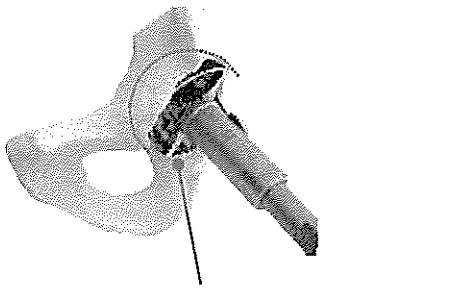



**Abb. 12a** Reaming depth

### 2.4.2 Implantation of metal shell cementless "BS"

The metal shell is been assembled with the inserter. Size of metal shell is respective to the Re-surfacing Nail® implant + 8 mm **(Fig. 13a)**.Then the metal shell can be positioned with reference to an inclination angle of 35° - 45° and an anteversion of 15° **(Fig. 13b)**.

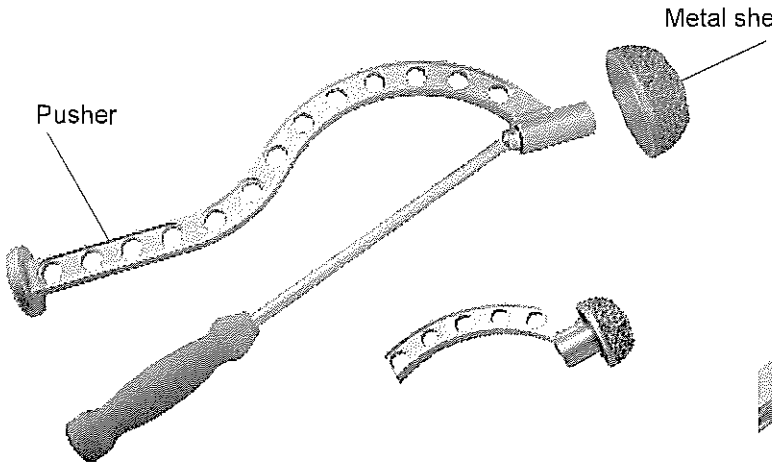



Fig. 13a

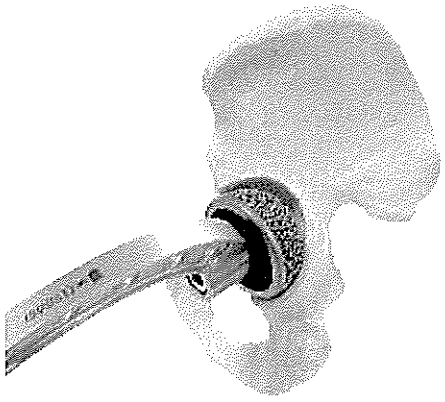


Fig. 13b **Mounting metal shell with pusher**

⚠ ***Note:***
*The closure screw must be unscrewed from the metal shell before assembly. When using ESKA Bionik®-System inserts without a centering guide the opening in the base of the shell can be closed again **(Fig. 14)**.*

Fig. 14 Allen key with closure screw for insert without centering guide

⚠ ***Important:***
***When using ESKA Bionik® System inserts with a centering guide (Fig. 15) the closure screw is not required.***

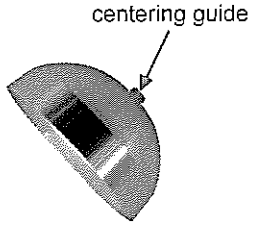



Fig. 15 Metal insert SILVER with centering guide

⚠ ***Note:***
Exentric beating can lead to deformation of the metal shell and is to avoid strictly. Deformation increases the abrasive wear caused by incorrect fit of the components. The metal shell is to be placed correctly into the anatomical acetabular rim.

## 2.5 Final preparation of the femoral head

This completes the preliminary preparation:

- The guide pin is replaced again **(Fig. 16a)**.
- The last selected resurfacing reamer is positioned.
- The femoral head is reamed incrementally to the definitive size **(Fig. 16b)**.

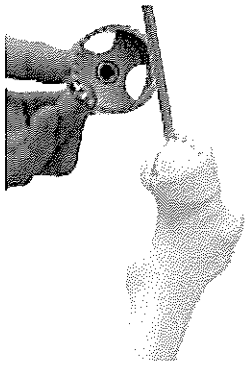


Fig. 16a

Fig. 16b

The position level is marked to set the insertion position of the resurfacing **(Fig. 17a, b)**. The reamer is removed and the marking gauge is inserted. In most cases the centre slot is selected. A higher or lower level (± 4 mm) can optionally be selected.

⚠ ***Note:*** *Use original ESKA saw blades with pins for marking only. The pins are used as stops.*

The resection is conducted after removal of the marker gauge **(Fig. 17c)**.

Fig. 17a

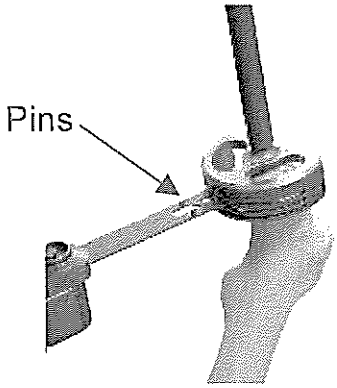



Fig. 17b

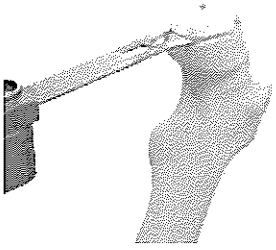


Fig. 17c

**Option:**
As an alternative to the resection the femoral head can be prepared with the flat reamer. A mark can be made with the cutting gauge for safety. Then the femoral head is reamed flat **(Fig. 18a)**. Observe the marks with reference to the leg length through the view window in the shaft (+4, 0, -4) **(Fig. 18b)**.

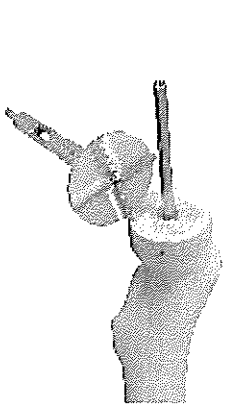


Fig. 18a

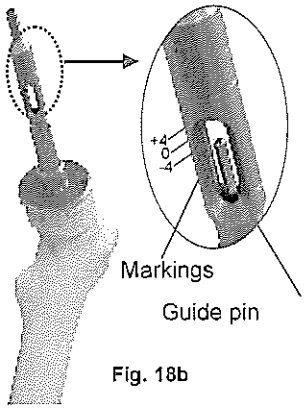



Fig. 18b

Then the surrounding bone margin is chamfered with the chamfer reamer of the relevant size **(Fig. 19a, b)**.

⚠ ***Important:* work to the stop of the reamer so the implant will reach the maximum seating depth.**

⚠ *Note: Preparation for type Cornwall see page 18.*

Remove the guide pin and widen the guide hole with the counter sink **(Fig. 20a, b)** to ensure a secure and flat base for the resurfacing.

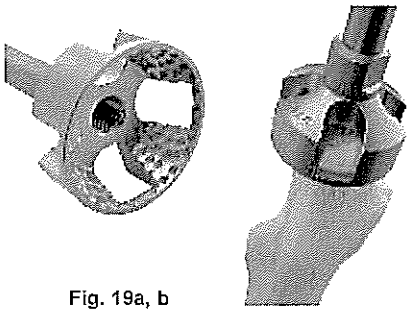


Fig. 19a, b

## Inspection resurfacing

After preparation of the femur the test inspection resurfacing is positioned **(Fig. 21)**. The hole in the inspection resurfacing is used to check that the resurfacing is in contact with the flat surface. When the seating is exact the final resurfacing position is marked **(Fig. 22)**.

This marking is used to check the resurfacing during implantation (seating depth).

⚠ ***Note:***
*The inspection resurfacing must be used for the trial reposition only in combination with a corresponding provisional insert not with the original implant.*

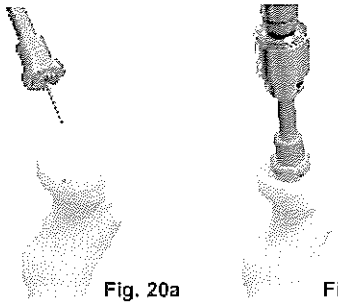


Fig. 20a



Fig. 20b

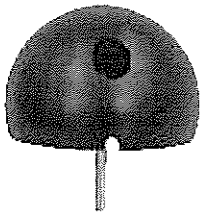


Fig. 21 Nail 3 mm

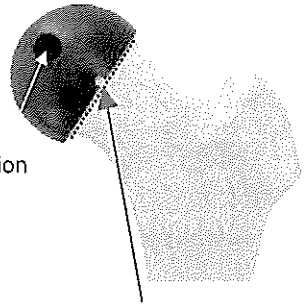



Fig. 22 Marking the seating depth of the resurfacing

## 2.6 Implantation of the Insert

**Manually placement of the insert**

If the metal shell is fixed position the insert manually avoiding wedging. Final conical fixation by hitting with the disposable PE-impactor **(Fig. 23a)**.

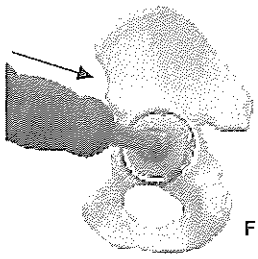


Fig. 23a Using the inserter

⚠ *Caution:*
*Only with a conical fixation without deformation of the metal shell or insert allows an easier revision with changing the insert.*

The position is to be verified by palpating and visual check.

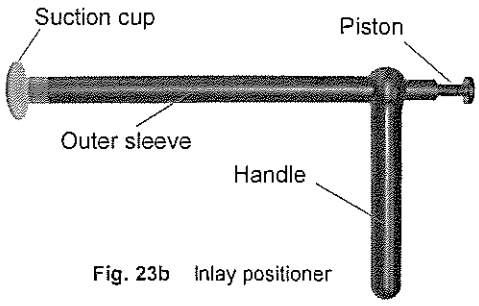



Fig. 23b Inlay positioner

Alternative:

***Instrumental placement of the insert***

*Instrument for positioning the insert **(Fig. 23b)**.*

⚠ *Note:*
*The ESKA inlay positioner is available on request.*

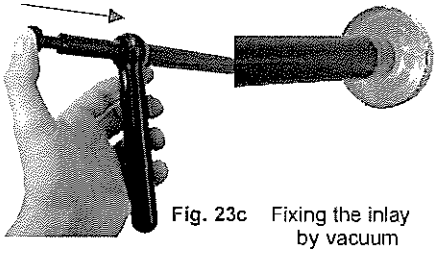


Fig. 23c Fixing the inlay by vacuum

*The ESKA inlay positioner is a special seating instrument for positioning inserts in the metal shell.*

*It consists of:*
- *Handle*
- *Outer sleeve*
- *Piston*
- *Suction cup*

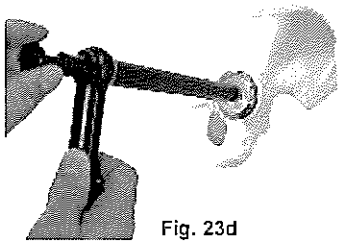


Fig. 23d

*The air is pressed out by pressing the piston down **(Fig. 23c)**. Then the suction cup of the positioner is pressed onto the insert and the piston is released.*

*The insert is clamp slightly by the vacuum **(Fig. 23g)**. Then the insert is inserted into the metal shell.*

⚠ *Caution: Do not tap in.*

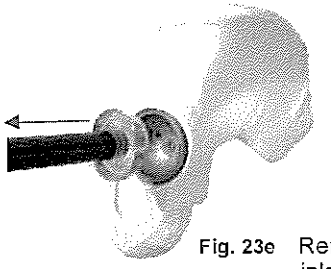


Fig. 23e Removing the inlay positioner

*The piston is pulled out to the stop to vent the instrument and to release the insert **(Fig. 23d)**. The positioner can be removed **(Fig. 23e)**.*

*Then the attachment that matches the internal diameter of the insert, which was supplied with the metal insert in sterile condition, is attached to the handle and the insert is tapped in **(Fig. 23a)**. After seating check visually and by feel that the seat is flush.*

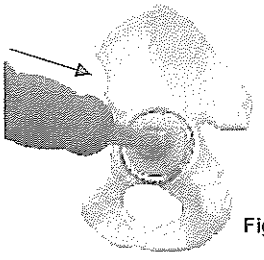


Fig. 23a Using the inserter

## 2.7 Implantation of the Femoral Resurfacing Nail®

### 2.7.1 Design

The femoral resurfacing is available in different designs. It is available in single components as well as pre-assembled.

The single component variant must be assembled first.

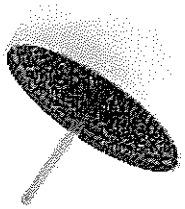


Fig. 24 CL BS Cream resurfacing with Nail D = 3 mm

<u>Pre-assembled design for directly implantation:</u>

- "CL" ESKA Cera-Metal® resurfacing **(Fig. 24)**/ "C" ESKA Cera Metal resurfacing (not shown)
  *These femoral resurfacings are available as a unit with Nail D = 3 mm.*

<u>Design single components:</u>

- C-SILVER resurfacing **(Fig. 25a)** or SILVER SURF resurfacing - modular (not shown)
- CL-SILVER resurfacing (not shown ) or SILVER SURF resurfacing - modular **(Fig. 25b)**
- CL resurfacing **(Fig. 25c)** Cornwall modular

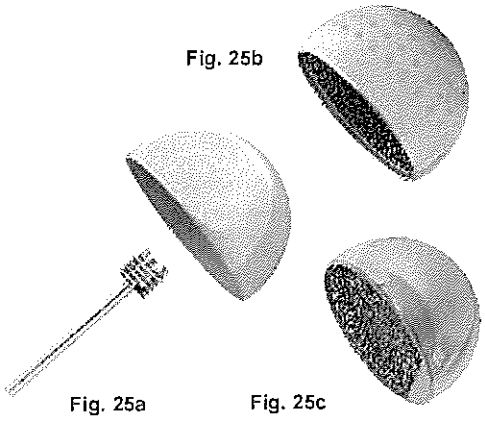


Fig. 25b

Fig. 25a

Fig. 25c

⚠ **Note:**
The modular resurfacing can be assembled with a "Nail D=3mm" or "Profi D=6mm"

### 2.7.2 Assembly of the modular resurfacing

⚠ After removal of the femoral resurfacing from the packaging (caution: protective attachment for femoral resurfacing is included in the packaging) the femoral resurfacing is gripped inside with the pliers **(Fig. 26)**. The femoral resurfacing is tensioned by rotating it clockwise**(Fig. 26a)**.

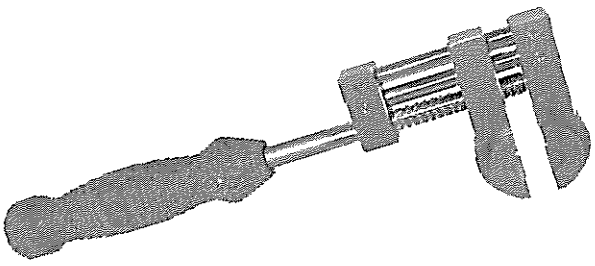


Fig. 26 Pliers

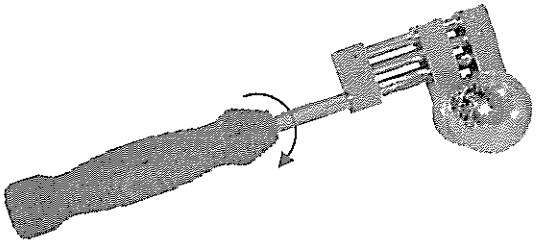


Fig. 26a Tensioning the femoral resurfacing

The "Nail" or "Profi" is manually screwed into the thread at the base of the femoral resurfacing. Tighten it with the "Nail" or "Profi" screwdriver. This crushes a plastic pin in the thread for a selflocking effect to fix the guide aid securely and reliably.

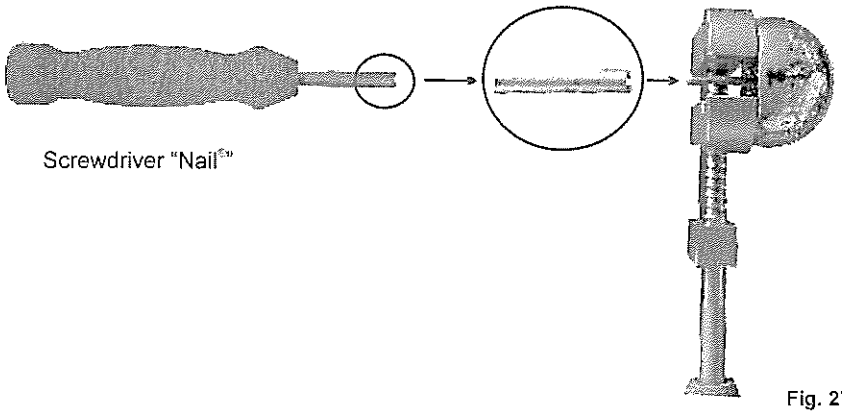



Fig. 27

### 2.7.3 Seating the implant manually

Assemble the protector which is supplied with the resurfacing implant in sterile condition with the pusher to cap it in position. Have the previously placed marking in mind during placing the implant (Fig. 28a, b).

Fig. 28a

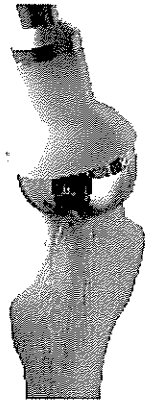


Fig. 28b

## 2. 8 Repositioning

Immediately after the implantation of the Hip Resurfacing Nail® the hip joint can be set. Finally the range of motion is checked to exclude an anterior or posterior impingement. In case of an impingement the bony parts have to be removed.

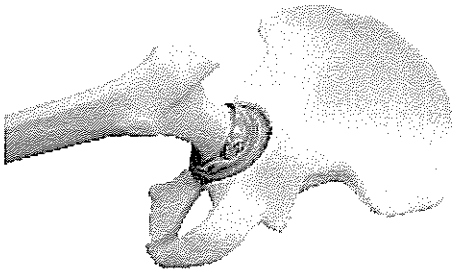


Fig. 29

## 2. 9 Wound closure

After the final inspection rinse out the complete wound area several times, place the drainage and close the wound in layers with a pressure dressing.

## 2.10 Preparation Type Cornwall

The model type Cornwall has a special internal geometry for offset correction. The cutting template is positioned according to the required offset correction **(Fig. a)**.

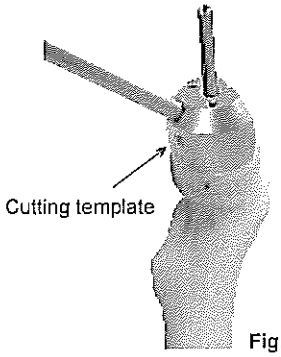



Fig. a

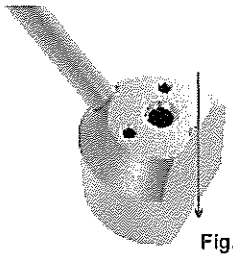
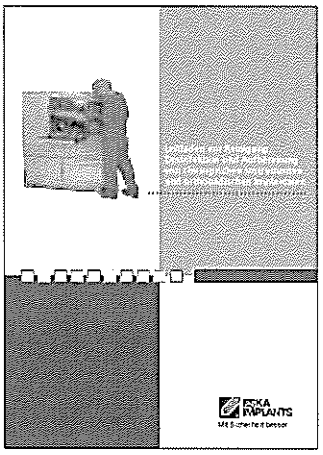


Fig. b

A slot **(Fig. b)** is milled into the straight face of the saw gauge to allow a colour marking to be placed on the femoral head, which can be used later to check the implant position.

## 3. Cleaning and resterilisation of the instrument set

For preparation of the ESKA instrument set please read our guide of cleaning, disinfection and preparation of surgical instruments and orthopaedic implants, which is available on request free of charge.

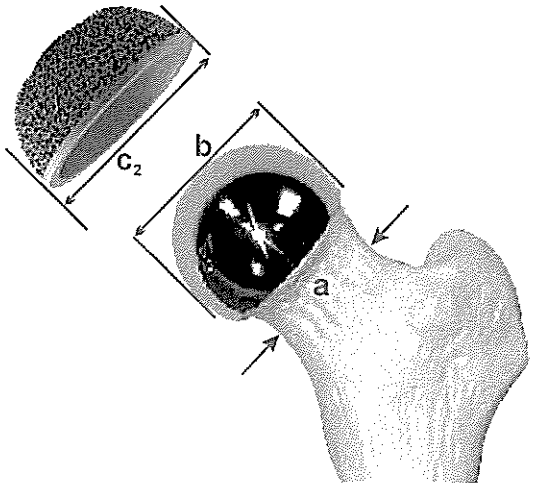


## 4. Precautions

The surgeon must be completely familiar with the warnings, precautions for use, indications, contraindications and adverse effects included in the package inserts. The package inserts are also available from ESKA Implants AG.

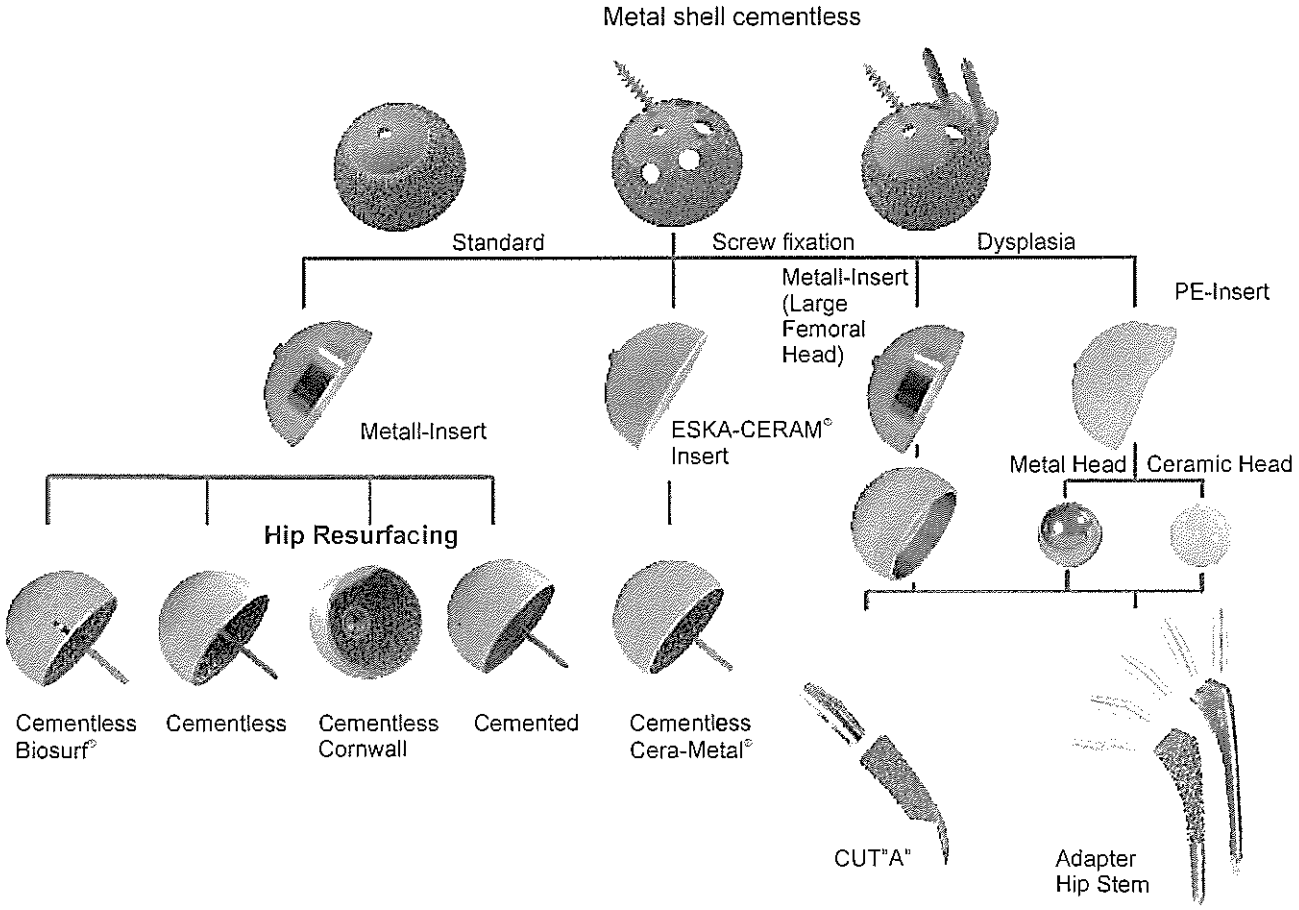
# Annex

## Size classification




| Femoral neck diameter Ø<br><br>[a] | Diameter of femoral resurfacing<br><br>[b] | Diameter of acetabulum reamer<br><br>[$c_1$] | Outside diameter of metal shell<br><br>*- Metal-insert*<br>*- ESKA-CERAM-insert*<br>*- PE-insert*<br><br>[$c_2$] |
|---|---|---|---|
| 24 | 38 | 44 | 46 |
| 26 | 40 | 46 | 48 |
| 28 | 42 | 48 | 50 |
| 30 | 44 | 50 | 52 |
| 32 | 46 | 52 | 54 |
| 34 | 48 | 54 | 56 |
| 36 | 50 | 56 | 58 |
| 38 | 52 | 58 | 60 |
| 40 | 54 | 60 | 62 |
| 42 | 56 | 62 | 64 |
| 44 | 58 | 64 | 66 |

## System concept



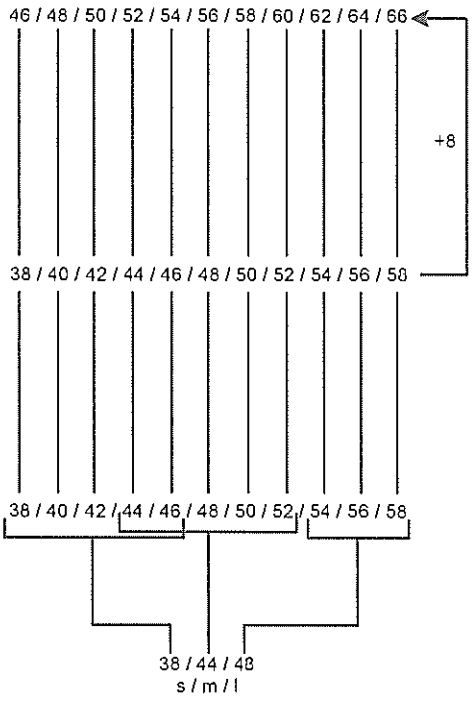
## Metal-on-Metal bearing option - size combi mix

Metal shell BS cementless
CoCrMo, TiNb-coated

Metal-Insert
CoCrMo (silver)

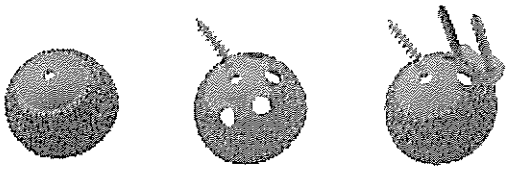
Hip Resurfacing cementless
Hip Resurfacing cemented
CoCrMo (silver)

Femoral Head Metal
CoCrMo (silver)



## Ceramic-on-Ceramic bearing option - size combi mix

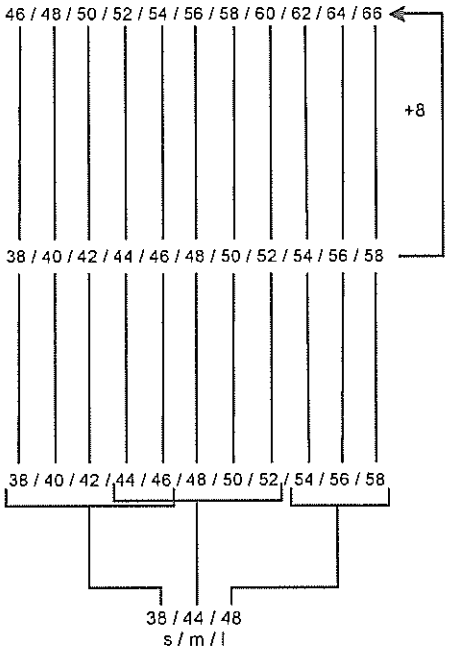
Metal shell BS cementless
CoCrMo, TiNb-coated

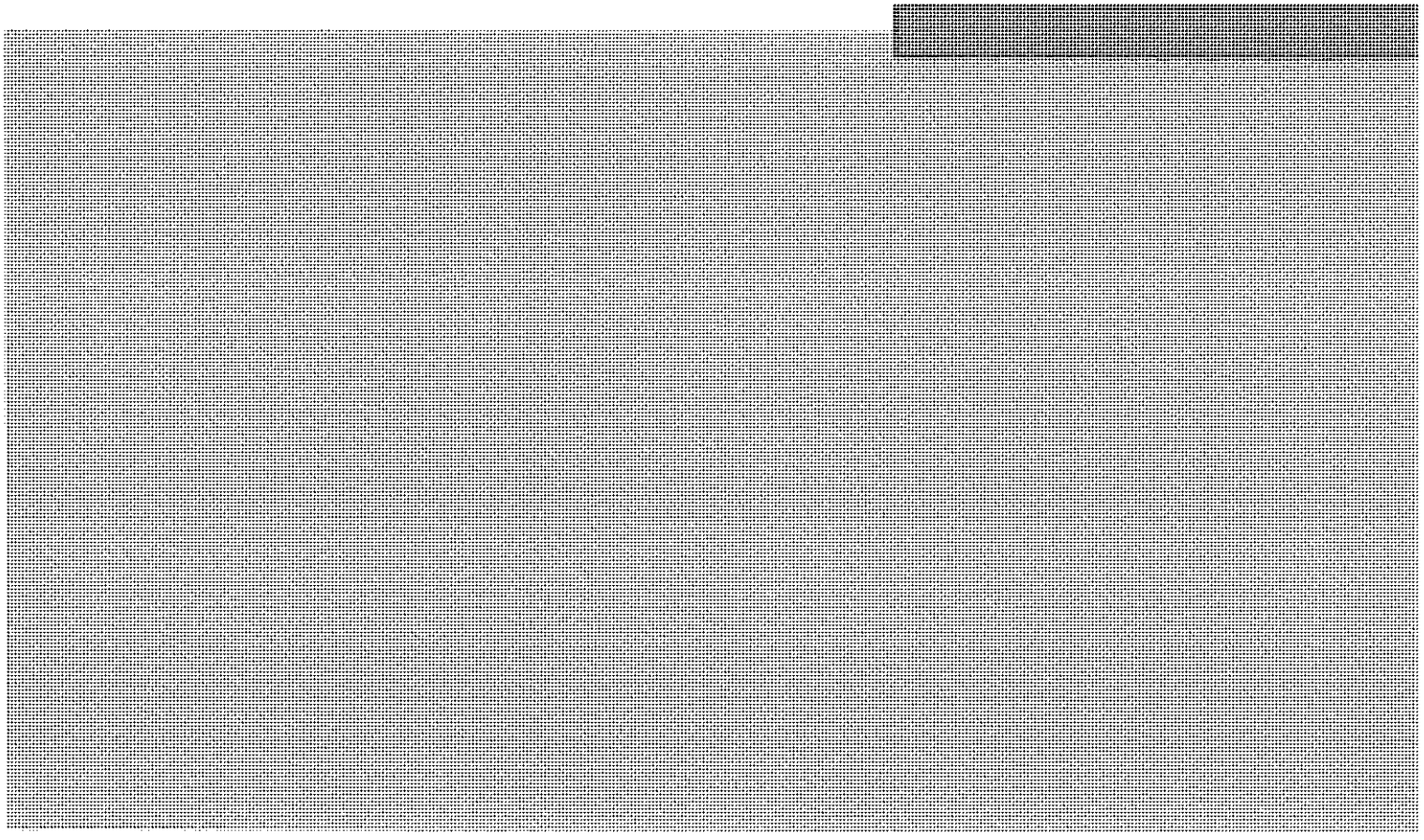


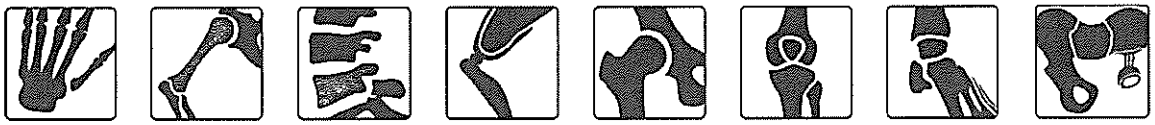
ESKA-Ceram®-Insert

Hip Resurfacing Cera-Metal®

Femoral Head large Cera-Metal®





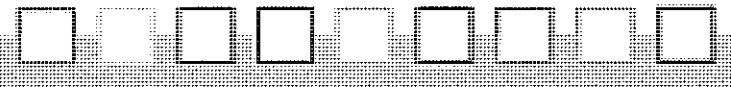


# Surgical Technique „Nail“

ESKA Genius® Hip-System – Hip Resurfacing ESKA Bionik®-System
Type “Standard“ and “Cornwall“







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