



**QUALITY WITHOUT COMPROMISE...**

## QUALITY STANDARDS FOR ST LEGER KNEE CASTINGS IN COBALT CHROME MOLYBDENUM

### **SPECIFICATION N°: MPC/GEN 7**

**SCOPE**

All St Leger Knee implants produced in cobalt chrome molybdenum alloy where no other standard is specified by the customer. This standard shall be submitted to the customer for approval prior to acceptance of an order.

**ASSOCIATED SPECIFICATIONS**

**BS 7252 Pt 4 (ISO 5832/4)** Metallic materials for surgical Implants. Specification for cobalt chromium molybdenum alloy.  
**BS 7254 Pt 5** – Orthopaedic Implants – Specification for production of castings made of cobalt chromium molybdenum alloy.  
**BS 18** Methods for tensile testing of metals (including aerospace materials).  
**BS 7731-** Radiographic Examination of Cast Metallic Surgical Implants.  
**BS 7730/ISO 9583** ‘Method for Liquid Penetrant Inspection of Metallic Surgical Implants.

**QUALITY CONTROL**

The latest issue of the above standards shall apply as at the date of receipt of order.  
 The manufacture of all castings shall be in accordance with the Quality Systems & Procedures of McKenna Group, which conform to **ISO 9001 & ISO 13485**  
 The casting process shall be validated for each type of casting.  
 Each casting is to be traceable to all production and test records.

**RAW MATERIAL**

The casting alloy shall be produced by induction melting. The composition of the ingot material shall be as follows. This composition complying with **BS 7252 Pt. 4**.



Element.	% Min	% Max
Chromium	27.0	30.0
Molybdenum	5.0	7.0
Nickel	-	1.0
Iron	-	0.75
Carbon	-	0.35
Manganese	-	1.0
Silicon	-	1.0
Nitrogen	0.18	0.22
Cobalt	Balance	

**No further additions shall be made after the final analysis sample has been taken.**



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### **INGOTS**

The dross level of the ingot shall be as low as possible so that minimal inclusions become entrapped within the casting.

Each raw material ingot shall be identified to ensure traceability to its master melt.

Ingots shall:

1. Be stored in an environment free from media that may contaminate the Material.
2. Be identified to prevent use of an incorrect alloy

### **CASTING METHOD**

Castings shall be produced by air melting in roll-over' furnace.

No other alloy type to be cast in the furnace liner prior to Cobalt-Chrome.

Moulds shall be clearly identified.

### **HEAT TREATMENT / TEST PIECES**

Castings shall be supplied in either the 'as cast' hipped or heat treated condition, as specified by the customer.

If heat treatment is specified the following processes shall be followed.

Castings shall be supplied in the solution annealed condition.

Temperature	<b>1200°C +/- 7°C</b>
Time	<b>4 hrs. +/- 10 mins.</b>
Atmosphere	<b>Vacuum (5 x 10 mbar)</b>
Cooling Type & Medium	<b>Rapid gas fan quench in an inert gas to below 100°C prior to exposure to atmosphere.</b>

**A heat treatment certificate shall be created for all heat treatment batches.**



## **MECHANICAL TESTS**

From each master melt tensile test bars shall be either cast with the castings or by the same casting process. These will be deemed to be representative of all the mould produced from the master melt.

Tensile properties required:

<b>U.T.S.</b>	<b>665 MPa Min.</b>
<b>0.2% Proof</b>	<b>450 MPa Min.</b>
<b>Elongation</b>	<b>8 % Min.</b>
<b>Red. Of Area</b>	<b>8 % Min.</b>
<b>Hardness</b>	<b>25 - 35 HRc.</b>

Hardness is given as a guideline only and shall not be used as a basis for rejection.

Two test pieces shall be tested in the as cast condition i.e. from the master melt.

One further test piece shall be tested, this test piece having been heat treated along with, and so be representative of a heat-treated batch of castings.

The tensile samples shall be proportional round test pieces gauge length **5.65 So.** (Where **So.** is the cross sectional area, and a minimum of **4mm**).

Should any of the original test bars fail to meet the specified requirement, two further test bars shall be tested. If either of the re-tests fail to meet the requirement of this standard the batch shall be deemed not to comply with this standard.

## **CHEMICAL ANALYSIS**

Chemical analysis shall be performed on the first and final melt of each batch of material and the results kept as a record.

## **ZONING OF PARTS**

It is the customer's responsibility to zone the applicable drawing to define critical & non-critical areas. Where the drawing does not specify critical areas the whole casting shall be classed as non-critical.



### **RADIOGRAPHIC EXAMINATION**

All castings shall be subject to radiographic examination.

Prior to radiography each casting shall be uniquely identified, this identity shall be identified on the radiographic report.

Radiographic examination shall be carried out in accordance with **BS 7731**- Radiographic Examination of Cast Metallic Surgical Implants.

Radiographic acceptance shall be based on comparison with **ASTM E 192** reference radiographs.

### **ACCEPTANCE STANDARDS**

Application of the reference radiographs shall be as follows:

Cracks, cold shuts, hot tears, filamentary shrinkage, piping and linear defects are not permitted.

A linear defect is defined as having a length to width ratio of **4 to 1**.

Acceptance shall be based on a comparison of the radiographs of cast product with the reference radiograph plate standards held in **ASTM E 192 PLATE 2**.

### **RETENTION OF X-RAY FILMS**

X-Ray films shall be sent to the customer with each delivery or make reference to the x-ray report number of previously sent x-ray films.

### **FLUORESCENT PENETRANT INSPECTION**

All castings shall be subject to **100%** fluorescent penetrant inspection.

Flaw Penetrant inspection is required in accordance with **BS 7730/ISO 9583**

'Method for Liquid Penetrant Inspection of Metallic Surgical Implants,  
Inspection Level 'B'.

Questionable or borderline indications shall be resolved by wiping the indications once with a swab or brush moistened with genklene or alcohol and then redeveloped. If the indication does not immediately re-appear, five minutes should be allowed to elapse prior to re-evaluation.

Acceptance shall be based on defect size and not indication size.

Acceptance Criteria - All Zones

1. Any linear defect where the length to width ratio is less than **4: 1**.
2. Isolated defects greater than 1 mm diameter are not acceptable. Isolated defects are defects separated by at least **10 times** the diameter of the largest defect.



**VISUAL EXAMINATION**

All castings shall be dry alumina blasted prior to inspection.

All castings shall be subject to **100%** visual examination.

**Acceptance Criteria. Defects contained within machine stock areas are acceptable. Machine stock areas to be advised by the customer.**

Non-Machined Areas	Critical Zone	Non-Critical Zone
Negatives	Accept up to <b>1mm dia. x 0.25mm dia. deep</b>	Accept up to <b>1mm dia. x 0.5mm dia. Deep.</b>
Positives	Accept up to <b>0.5mm dia. x up to 0.5 mm high</b>	Accept up to <b>1mm dia. x 1mm high</b>
Quantity	Up to 4 defects within an area of <b>10mm<sup>2</sup></b>	Up to 4 defects within an area of <b>10mm<sup>2</sup></b>
Parting Line	Up to <b>0.2mm</b>	Up to <b>0.2mm</b>

**Critical and Non-Critical Zones to be advised by the customer.**

**RECTIFICATION OF DEFECTS**

Defects may be blended out provided the casting remains within the casting drawing tolerances.

Max. permitted weld cavity **6mm dia. x 1.0mm** deep after weld preparation.

Where welding has taken place, post welding heat treatment shall be carried out as follows:

Temperature	<b>1200°C +/- 7°C</b>
Time	<b>4 Hours +/- 10 Mins.</b>
Atmosphere	<b>Vacuum (5 x 10 mbar)</b>
Cooling Type & Medium	<b>Rapid Gas Fan Quench in an inert gas to below 100°C prior to exposure to atmosphere.</b>

Any casting requiring recovery by welding shall be subjected, after post welding heat treatment, to inspection by the same NDT method by which the original defect was detected.

Weld repair shall exclude repairs in regions specified by the customer to be in regions of high stress in service.



#### **CONDITION OF SUPPLY**

Castings shall be supplied in the Alumina Grit Blasted condition using non-ferrous media unless otherwise specified.

#### **METALLOGRAPHIC EXAMINATION**

Where certification to **BS 7254 Part 5** is a specified requirement, then the following metallurgical examination shall be carried out.

At the initiation of the casting process for a new design of product or on subsequent major design or process change that may affect the metallurgy of the casting, the castings shall be metallographically examined to determine that no abrupt change in grain size or other detrimental metallographic features occur in regions expected to be most highly stressed in service.

#### **CERTIFICATE OF CONFORMITY**

A certificate of Conformity shall be supplied with every batch of castings supplied to the customer.

This Certificate of Conformity shall refer to,

1. The quantity of castings supplied
2. The X-Ray serial numbers and report
3. The material certification including a statement of compliance to **BS 7252 Pt.4**.
4. Mechanical test results
5. The purchase order number
6. A statement as to the 'as cast', hipped or heat treated condition of the castings.

#### **LATENT DEFECTS**

Up to **3%** latent defects will be accepted by the customer on as cast products.

A **3 month** maximum liability period applied to all castings from the date of delivery to the customer site. This ensures rapid feedback and corrective action of potential problems.

#### **RECORDS RETENTION**

All records relating to the manufacture of surgical implant castings shall be retained at MPC for a minimum of **30 years**, unless otherwise agreed with the customer.