X SIGNATURE Agluna"LRS

No Revision for Revision



#Revisionredefined

Revision THR Infection

Key Findings from a Retrospective Study (1990-2004)#

Primary Total Hip Arthroplasty (THA)

• Advancements in technology have successfully decreased infection rates.

Revision Surgeries

• Despite advancements, there has been a troubling **266%** increase in infection rates.





on A Rising Concern!

Critical Findings from UK Hospitals*

Study Scope

- Analysis of 102 hospitals
- 24,808 hip arthroplasty operations

Infection Rates

• 18.2% of hip re-revisions are due to infections



Implications

• Highlights the critical need for improved post-revision infection management

Emphasizes the higher infection risk in revision hip arthroplasty compared to primary procedures

Re-revision Reasons in Hip Arthroplasty (2003 - 2022)

- Infection Re-revision
- Aseptic Loosening Re-revision
- Dislocation/Subluxation Re-revisions
- Other Reasons







Minimizes infection and maximizes longevity of revision surgery.

Surface Modification

-Stores silver ions for controlled release. -Not a coating, but advanced surface modification.

Antimicrobial Effect:

A silver surface that helps prevent periprosthetic infections, complementing but not replacing standard antibiotic regimens.

Innovative Surface Technology*

Enhanced Durability:

Improves base material properties without compromising design and functionality.

Reduced Complications:

Minimizes the risk of coating delamination for reliable performance.

*Ref- http://www.testing-engineers.com/coating.pdf

Silver as an Antimicrobial Agent in the Clinical Setting



Effective Infection Control Silver's antimicrobial properties

reduce infection incidences.



Durable Protection Provides long-lasting antimicrobial effects.



Broad-Spectrum Action

Targets bacteria, fungi and viruses.



Biocompatible Well-tolerated by human tissues.

*Ref- Thurman RB and Gerba CP, The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses, CRC Critical Reviews in Environmental Control, 18(4), 295-315, 1989.

*Ref- Russell AD and Hugo WB, Antimicrobial activity and action of silver, Progress in Medicinal Chemistry, 31, 351-370, 1994.

SIGNATURE AGLUNA"

Surface Technology

The Agluna[™] treatment for implants uses an electrochemical process involving high voltage anodization of titanium in phosphoric acid, followed by silver ion exchange. This creates circular features on the implant surface that store ionic silver, making it a surface modification rather than a coating.



Mode of Action of Silver Ion on Agluna™ Treated Signature LRS

- The Agluna[™] Process uses antimicrobial silver ions to combat biofilm & reduce post-op infections.
- Silver ions, known for their bactericidal properties, offer a safe & effective infection prevention solution.

Signature Agluna™LRS: Advanced Silver Ion Technology for Infection Control



Long Revision Stem

 12/14 Taper Circulotrapezoidal neck to provide greater range of motion

Wide range of stem & diameter

Conical Design Prevents subsidence of stem

Circular cross-section Free setting of anteversion Canal preparation made possible with reamers for protection and preservation of bone

> --- Small stem diameter for better fit in metaphyses

> > 2° tapered design For press fit operation

8 longitudinal ribs • for rotational stability and fixation in cortical bone

Active silver ion treatment •

on entire surface to prevent infection

Verifications and Validations

Safety and Efficacy Performance Characteristics



Minimum Inhibitory Concentration Tests & Efficacy of Silver Ion

Silver lons are effective against

- Staphylococcus aureus,
- Coagulase-negative Staphylococci,
- Pseudomonas aeruginosa,
- Escherichia coli,
- Enterococcus faecalis,
- Streptococcus pyogenes,
- Aspergillus fumigatus,
- Candida albicans
- Klebsiella pneumonia.

No resistance found against the above mentioned bacteria's.⁽¹⁾

Zone of Inhibition

Samples treated with agluna showed a clear zone of inhibition against methicillin-resistant Staphylococcus aureus (MRSA), indicating agluna's effectiveness in preventing MRSA growth. This suggests agluna could be valuable in combating antibiotic-resistant bacteria like MRSA.



Osseointegration

Comparable to standard gritblast surfaces at 12 weeks.⁽⁶⁾⁽⁷⁾



Antibacterial Activity

Agluna[™]-treated samples effective against all nine tested organisms per ISO 22196 and ASTM E2315 guidelines.⁽²⁾



Elution

Silver ion release from Agluna[™]-treated stems matches CE Marked standards, maintaining characteristics over five years.⁽³⁾



Pharmacokinetics

Less than 2% of silver distributed in organs, non-toxic.⁽⁵⁾



Biocompatibility

Passed ISO 10993-1 tests including cytotoxicity, sensitization, irritation, and genotoxicity.⁽⁸⁾⁻⁽¹⁴⁾

Agluna[™] Manufacturing Process Validation

- The Agluna[™] process is operated by Accentus Medical at its UK-based ISO13485:2016 accredited manufacturing facility.
- The Agluna[™] processing plant has been validated in accordance with regulatory requirements.
- A Performance Qualification study has been carried out demonstrating process validation for application of Agluna[™] technology to the Signature LRS.⁽¹⁵⁾

Specifications

Length Ø mm	200mm	245mm	275mm
12	✓	✓	NA
13	✓	✓	NA
14	✓	✓	✓
15	✓	✓	✓
16	✓	✓	✓
17	✓	✓	√
18	✓	✓	✓



Ref-

(1) Accentus Medical Reports ZRR_ZB_0005_09, 2009; ZRR_ZB_0007_10, 2010; ZRR_ZB_0020_09, 2009; ZRR_WA_2658_12, 2012.

(2) Accentus Medical Report ZRR_WA_2965_15, 2015.

- (3) Accentus Medical Report AGT07-DVer.059, 2015.
- (4) Accentus Medical Report ZB-TEA-002, M22420, 2008.
- (5) Accentus Medical Report ZRR_WA_2782_14, 2015.
- (6) Accentus Medical Reports ZTR_WA_0237_14, 2014 (Co-authorship includes J. Parvizi); ZRR_WA_2744_13, 2015.
- (7) Osseointegration of Silver Treated Titanium Alloy, ORS Poster, University College London / Accentus Medical, 2012.
- (8) Accentus Medical Report #189292 (WuxiApptec), 2013.
- (9) Accentus Medical Report #189287 (WuxiApptec), 2013.
- (10) Accentus Medical Report #189284 (WuxiApptec), 2013.
- (11) Accentus Medical Report #189286 (WuxiApptec), 2013.
- (12) Accentus Medical Reports #180054, #180055, #188188, #188187 (WuxiApptec), 2014.
- (13) Accentus Medical Reports #189283, #189285, #189288 (WuxiApptec), 2013.
- (14) Accentus Medical Report #189289 (WuxiApptec), 2013.
- (15) Accentus Medical Report AGT12-VAL.086, 2023.

To Know More Scan:





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