

**THE NEXT GENERATION
ANTIMICROBIAL GRAFT
INTERGARD SYNERGY**



INTERGARD SYNERGY THE NEXT GENERATION ANTIMICROBIAL GRAFT MAQUET – THE GOLD STANDARD



Consistent with MAQUET Vascular Interventions' policy of continuous improvement, the company has sought to develop an antimicrobial graft with increased efficacy than that of the current INTERGARD SILVER. The resultant product, INTERGARD SYNERGY, is made of polyester and coated with a highly purified form of cross-linked bovine collagen to minimize intra-operative bleeding and eliminate the need for preclotting at the time of implant. In addition to collagen, the INTERGARD SYNERGY vascular prosthesis comprises silver acetate and triclosan, providing improved antimicrobial properties without compromising safety.

In the test protocols, the INTERGARD SYNERGY vascular prosthesis demonstrated antimicrobial efficacy against a broad spectrum of microorganisms including MRSA (Methicillin Resistant Staphylococcus Aureus). In addition, it was also shown that the INTERGARD SYNERGY vascular prosthesis was substantially more effective when compared against the predicate device INTERGARD SILVER.

This new antimicrobial graft, combining those two well-known antimicrobial agents, silver acetate and triclosan should be considered an adjunct to current surgical practice.

MAQUET – The Gold Standard.



INTERGARD SYNERGY

THE NEXT GENERATION ANTIMICROBIAL GRAFT

Consistent with MAQUET's continuous innovation policy,

INTERGARD SYNERGY is the first vascular prosthesis combining two well-known antimicrobial agents: silver acetate and triclosan. While those antimicrobial agents are effective alone, their power to prevent development of infection intensifies when combined, offering increased antimicrobial properties than the existing available vascular prosthesis on the market.

About graft infections

- 40-75% amputation rate and 25-75% mortality rate.^{1,3,4}
- Rates of incidence range from 1-6%.^{2,3,4}
- Greater than 90% of patients have one or more risk factors for the development of graft infection.⁷

Severe economic impact of vascular graft infection

- The estimated cost of combined medical and surgical treatment of infections associated with vascular grafts is \$40,000.⁸
- Cost to treat an infected vascular graft is more than 3 times the cost of the original surgical procedure.⁵

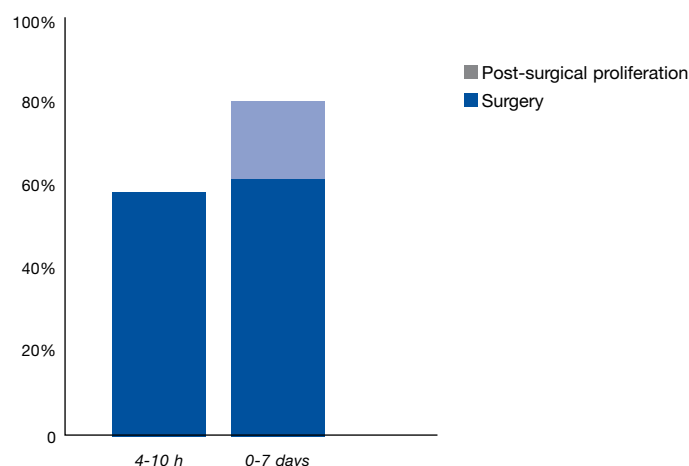
The majority of vascular graft infections occur at the time of implant, or in the immediate postoperative period⁹

- The release profile of the combined silver and triclosan is designed to be most active during the initial 24 hours post implant, with continuous and substantial release for a 6 days period.⁶
- In vitro and in vivo testings have proven the effectiveness of INTERGARD SYNERGY against a broad spectrum of microorganisms including MRSA and Staph Epi, with sustained effectiveness beyond 7 days.^{6,7}

REFERENCES

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3. Szilagyi DE, Smith RF, Elliot JP, et al. Infection in arterial reconstruction with synthetic grafts. *Ann Surg.* 1972 Sept; 176(3): 321-33.
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9. Ricco JB, Assadian A, Schneider F, Assadian O., *In vitro* evaluation of the antimicrobial efficacy of a new silver-triclosan vs a silver collagen-coated polyester vascular graft against methicillin-resistant *Staphylococcus aureus*., *J Vasc Surg.* 2012 Mar; 55(3):823-9.
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Risk of vascular graft infection^{1,7}



SYNERGY ULTRATHIN

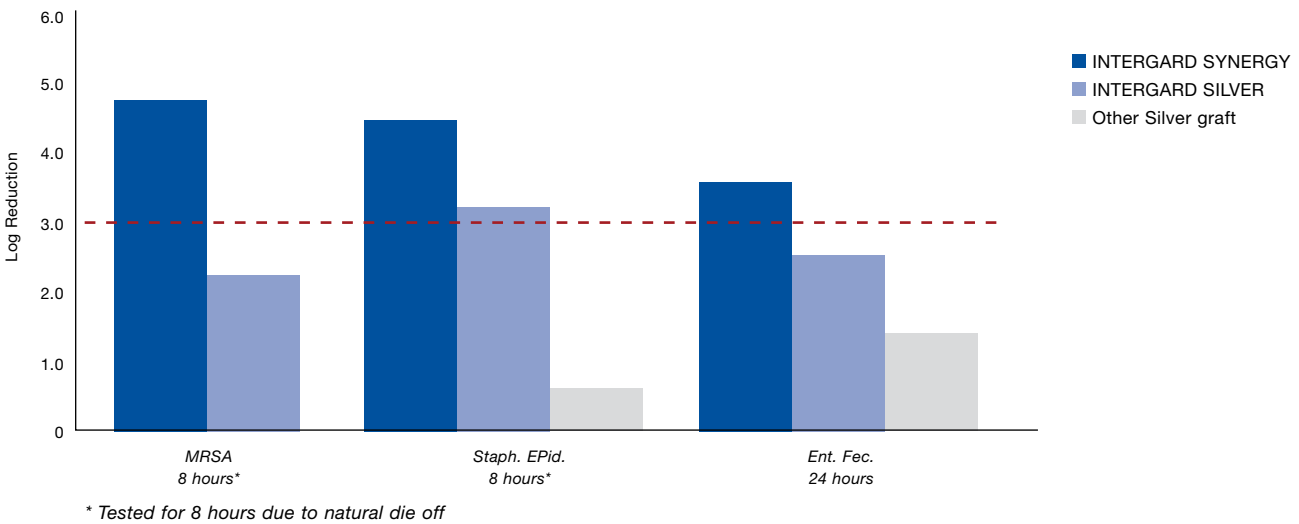
INTERGARD SYNERGY is available in a large range of configuration including Knitted, and UltraThin. The proprietary ultra thin wall construction of INTERGARD SYNERGY UltraThin produces a small diameter graft with exceptional handling and suturing characteristics. With a wall thickness of just 0.35 mm, INTERGARD SYNERGY UltraThin is one of the thinnest antimicrobial peripheral graft on the market. The unique polyester matrix creates a compliant vessel due to its pulsatility.

INTERGARD SYNERGY UltraThin is available in configurations specially designed for peripheral procedures where the incidence of graft infection is highest.

- Radial and longitudinal pulsatility
- No suture hole bleeding
- Excellent host vessel conformability
- Available with optional radial support

FACTS ON INTERGARD SYNERGY

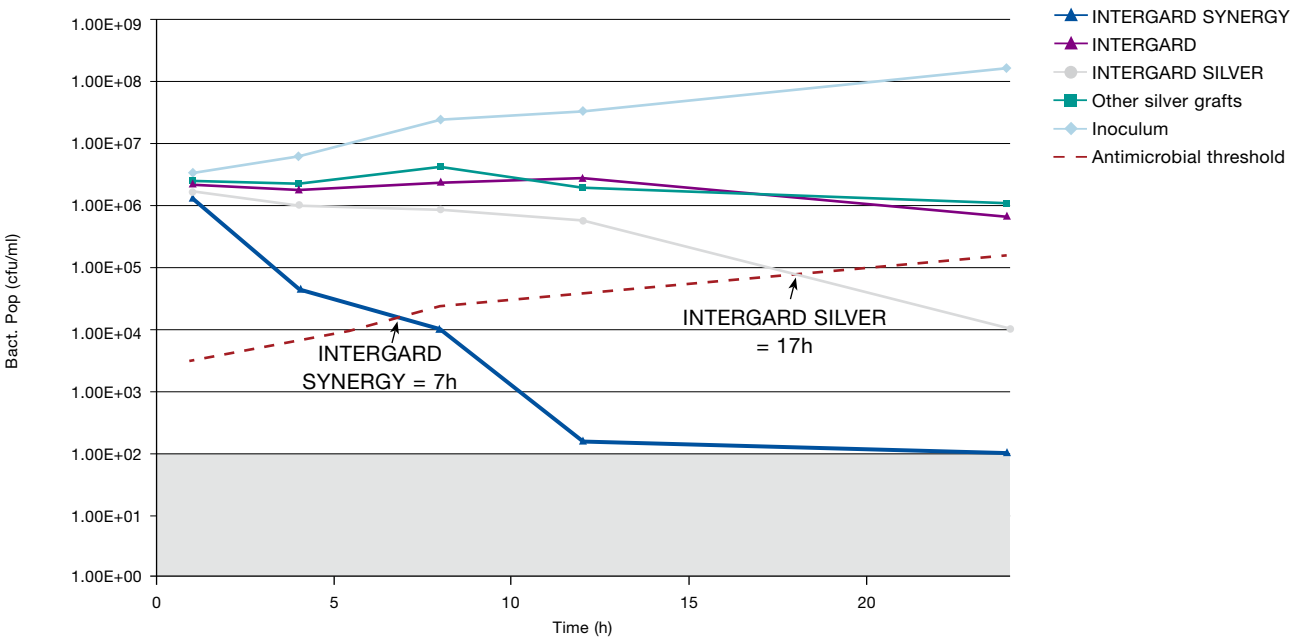
ASTM E2149 Bacterial Population LOG Reduction ⁶



ASTM E 2149 test method, formerly known as Dow Corning Shake Flask Test, is designated to evaluate the resistance of non-leaching antimicrobial treated specimens to growth of bacteria under dynamic contact conditions.

INTERGARD SYNERGY shows higher efficacy, especially on MRSA, compared to INTERGARD SILVER or other silver grafts available on the market.

Kill time test results against MRSA ⁶



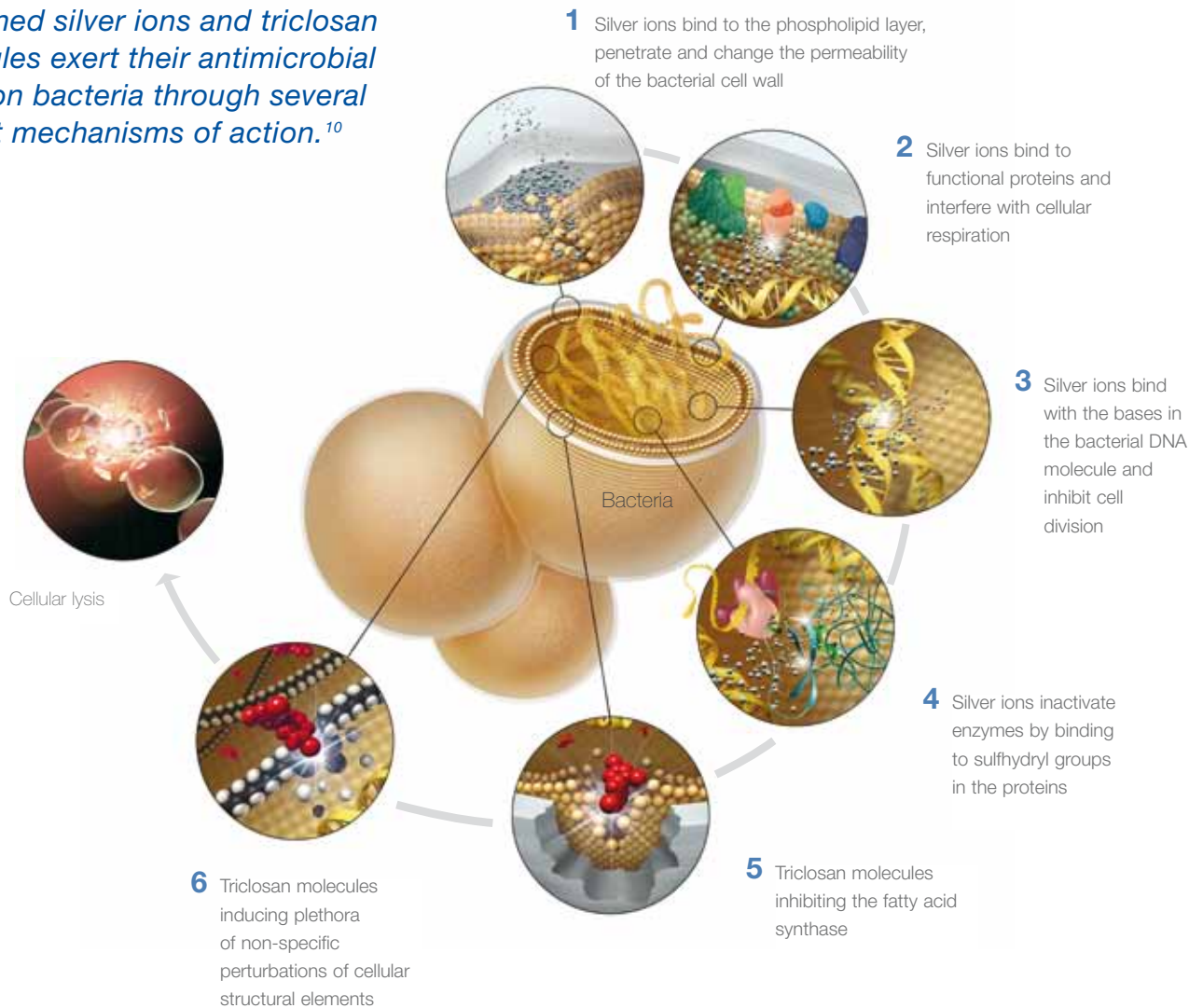
Kill time test is a quantitative contact test to determine the number of viable micro-organisms present on the graft after various exposure times. While both INTERGARD and SYNERGY INTERGARD SILVER showed bactericidal efficacy against MRSA in this standard in vitro method ⁹, INTERGARD

SYNERGY shows significant colony count reduction. The antimicrobial threshold is reached significantly faster with INTERGARD SYNERGY compared to any antimicrobial graft available on the market. Both grafts showed bactericidal efficacy against MRSA in this standard in vitro method.

INTERGARD SYNERGY

THE NEXT GENERATION ANTIMICROBIAL GRAFT

Combined silver ions and triclosan molecules exert their antimicrobial effect on bacteria through several distinct mechanisms of action.¹⁰



PHYSICAL AND MECHANICAL PROPERTIES*

| | Knitted | UltraThin |
|--------------------------------|--|--|
| Coated polyester fabric | Cross-linked Type I bovine collagen | Cross-linked Type I bovine collagen |
| Construction | Knitted, external velour, reverse locknit | Knitted, reverse locknit |
| Water permeability | $\leq 5\text{ml} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}@120\text{ mmHg}$ | $\leq 5\text{ml} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}@120\text{ mmHg}$ |
| Wall thickness** | 0.49 mm | 0.35 mm |
| Burst strength** | 32.7 kg/cm ² | 35.3 kg/cm ² |
| 45°suture retention** | 3.37 kg | 1.83 kg |

* Testing performed per ANSI/AAMI/ISO 7198:1998/2001.

** Test results are for customer evaluation only and do not represent a product specification.

INTERGARD SYNERGY PRODUCT INFORMATION

INTERGARD SYNERGY KNITTED

STRAIGHT GRAFTS

20 cm length:

| Diameter | Reference |
|----------|---------------|
| 6 mm | IGK0006-20SG |
| 8 mm | IGK0008-20SG |
| 12 mm | IGK00012-20SG |
| 14 mm | IGK00014-20SG |
| 16 mm | IGK00016-20SG |
| 18 mm | IGK00018-20SG |
| 20 mm | IGK00020-20SG |
| 22 mm | IGK00022-20SG |
| 24 mm | IGK00024-20SG |

40 cm length:

| Diameter | Reference |
|----------|--------------|
| 6 mm | IGK0006-40SG |
| 7 mm | IGK0007-40SG |
| 8 mm | IGK0008-40SG |
| 10 mm | IGK0010-40SG |
| 12 mm | IGK0012-40SG |
| 14 mm | IGK0014-40SG |
| 16 mm | IGK0016-40SG |
| 18 mm | IGK0018-40SG |
| 20 mm | IGK0020-40SG |
| 22 mm | IGK0022-40SG |
| 24 mm | IGK0024-40SG |

70 cm length:

| Diameter | Reference |
|----------|--------------|
| 6 mm | IGK0006-70SG |
| 7 mm | IGK0007-70SG |
| 8 mm | IGK0008-70SG |
| 10 mm | IGK0010-70SG |

RADIALLY SUPPORTED GRAFTS

| Diameter | Proximal Length | Supported Length | Distal Length | Total Length | Reference |
|----------|-----------------|------------------|---------------|--------------|------------------|
| 6 mm | 35 cm | 20 cm | 15 cm | 70 cm | IGK0006RS20SG |
| 6 mm | 25 cm | 30 cm | 15 cm | 70 cm | IGK0006RS30SG |
| 6 mm | 20 cm | 45 cm | 20 cm | 85 cm | IGK0006RS45SG |
| 8 mm | 12.5 cm | 15 cm | 12.5 cm | 40 cm | IGK0008RS15-40SG |
| 8 mm | 40 cm | 15 cm | 15 cm | 70 cm | IGK0008RS15SG |
| 8 mm | 35 cm | 20 cm | 15 cm | 70 cm | IGK0008RS20SG |
| 8 mm | 25 cm | 30 cm | 15 cm | 70 cm | IGK0008RS30SG |
| 8 mm | 20 cm | 45 cm | 20 cm | 85 cm | IGK0008RS45SG |
| 8 mm | 20 cm | 60 cm | 20 cm | 100 cm | IGK0008RS60SG |
| 10 mm | 15 cm | 10 cm | 15 cm | 40 cm | IGK0010RS10-40SG |

BIFURCATED

50 cm length:

| Diameter | Reference |
|----------|-----------|
| 12x6 mm | IGK1206SG |
| 14x7 mm | IGK1407SG |
| 16x8 mm | IGK1608SG |
| 18x9 mm | IGK1809SG |
| 20x10 mm | IGK2010SG |
| 22x11 mm | IGK2211SG |
| 24x12 mm | IGK2412SG |

INTERGARD SYNERGY KNITTED ULTRATHIN

ULTRATHIN RADIALLY SUPPORTED

| Diameter | Proximal Length | Supported Length | Distal Length | Reference |
|----------|-----------------|------------------|---------------|--------------------|
| 6 mm | 35 cm | 20 cm | 15 cm | IGKUT0006RS20SG |
| 6 mm | 25 cm | 30 cm | 15 cm | IGKUT0006RS30SG |
| 7 mm | 35 cm | 20 cm | 15 cm | IGKUT0007RS20SG |
| 7 mm | 25 cm | 30 cm | 15 cm | IGKUT0007RS30SG |
| 8 mm | 15 cm | 10 cm | 15 cm | IGKUT0008RS10-40SG |
| 8 mm | 12.5 cm | 15 cm | 12.5 cm | IGKUT0008RS15-40SG |
| 8 mm | 40 cm | 15 cm | 15 cm | IGKUT0008RS15SG |
| 8 mm | 35 cm | 20 cm | 15 cm | IGKUT0008RS20SG |
| 8 mm | 25 cm | 30 cm | 15 cm | IGKUT0008RS30SG |

ULTRATHIN

40 cm length:

| Diameter | Reference |
|----------|----------------|
| 6 mm | IGKUT0006-40SG |
| 7 mm | IGKUT0007-40SG |
| 8 mm | IGKUT0008-40SG |

70 cm length:

| Diameter | Reference |
|----------|----------------|
| 6 mm | IGKUT0006-70SG |
| 7 mm | IGKUT0007-70SG |
| 8 mm | IGKUT0008-70SG |

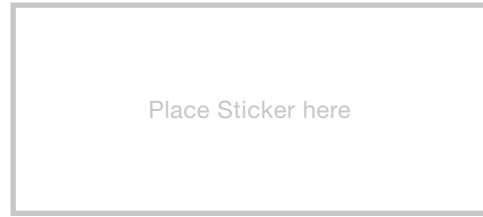
AXILLO-BIFEMORAL GRAFTS

| Diameter Length | Supported Length (body/branch) | Total Length (body/branch) | Reference |
|-----------------|--------------------------------|----------------------------|--------------------|
| 8x8 mm | | 100x60 cm | IGKAX0808SG |
| 8x8 mm | 45x20 cm | 85x55 cm | IGKAX0808RS45/20SG |
| 8x8 mm | 45x30 cm | 85x55 cm | IGKAX0808RS45/30SG |
| 8x8 mm | 60x30 cm | 100x55 cm | IGKAX0808RS60/30SG |

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