

PUSHING BOUNDARIES

Terumo Interventional Systems **broadens your reach** with new tools and techniques in interventional medicine.

We're relentlessly seeking new ways to help you apply effective solutions and achieve **better outcomes for more patients.**



Angio-Seal®

Vascular Closure Device

ORDERING INFORMATION

ANGIO-SEAL VIP		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
610130	6	0.035
610131	8	0.038
ANGIO-SEAL EVOLUTION™		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
C610134	6	0.035
C610135	8	0.038
ANGIO-SEAL STS PLUS		
PRODUCT CODE	FRENCH SIZE	GUIDEWIRE DIAMETER (in)
610119	6	0.035
610121	8	0.038

Contents: Vascular Closure Device, Insertion Sheath, Arteriotomy Locator and 70 cm Guidewire with "J" Straightener (10 units per box).

FIND OUT MORE ☎ Phone: 800.862.4143 🌐 terumo.com 📠 Fax: 800.411.5870

Indications

The Angio-Seal Vascular Closure Device product family, including the STS Plus, VIP and Evolution platforms, is indicated for use in closing and reducing time to hemostasis of the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller procedural sheath for the 8 F Angio-Seal device and a 6 French or smaller procedural sheath for the 6 F Angio-Seal device. The Angio-Seal STS Plus, VIP and Evolution platform devices are also indicated for use to allow patients who have undergone diagnostic angiography to safely ambulate as soon as possible after sheath removal and device placement, as well as to allow patients who have undergone an interventional procedure to safely ambulate after sheath removal and device placement.

Important Safety Information

Possible adverse events for vascular closure devices include, but are not limited to: bleeding or hematoma, AV fistula or pseudoaneurysm, infection, allergic reaction, foreign body reaction, inflammation or edema. This device should only be used by a licensed physician (or other health care professional authorized by or under the direction of such physician) possessing adequate instruction in the use of the device, e.g., participation in an Angio-Seal physician instruction program or equivalent.

RX ONLY. Refer to the product labels and package insert for complete warnings, precautions, potential complications, and instructions for use.

References:

1. Kussmaul WG 3rd, Buchbinder M, Whitlow PL, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: results of a randomized trial of a novel hemostatic device. *J Am Col Cardiol*. 1995;25(7):1685-92.
2. Nash JE, Evans DG. The Angio-Seal™ hemostatic puncture closure device. Concepts and experimental results. *Herz*. 1999;24(8):597-606.
3. Applegate RJ, Turi Z, Sachdev N, et al. The Angio-Seal Evolution Registry: outcomes of a novel automated Angio-Seal vascular closure device. *J Invasive Cardiol*. 2010;22(9):420-6.
4. Data on file.
5. Tellez A, Cheng Y, Yi GH, et al. *In vivo* intravascular ultrasound analysis of the absorption rate of the Angio-Seal™ vascular closure device in the porcine femoral artery. *EuroIntervention*. 2010;5(6):731-6.
6. Aker UT, Kensey KR, Heuser RR, Sandza JG, Kussmaul WG 3rd. Immediate arterial hemostasis after cardiac catheterization: initial experience with a new puncture closure device. *Catheter Cardiovasc Diagn*. 1994;31(3):228-32.
7. Applegate RJ, Rankin KM, Little WC, Kahl FR, Kutcher MA. Restick following initial Angioseal use. *Catheter Cardiovasc Interv*. 2003;58(2):181-184.

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Angio-Seal®

Vascular Closure Device

THE INSIDE ADVANTAGE™

Bioabsorbable + Dual Security



HELP ENSURE
SUCCESSFUL HEMOSTASIS

The ANGIO-SEAL active closure anchor gives you the inside advantage. The anchor creates a mechanical seal from the inside out—here’s how:

- **The anchor supports proper location for a reliable seal and collagen positioning^{1,2}:**
99.7% deployment success³
97.8% hemostasis by device³
- **The anchor and seal are bioabsorbed:**
 - Fibrin coats the anchor within hours and becomes totally encapsulated in 7-14 days⁴
 - Anchor begins to hydrate and soften 24-36 hours after deployment⁴
 - Anchor is absorbed 95% at 42 days⁵
 - All components are absorbed within 60-90 days^{1, 2, 6, 7}
- **Arterial flow is not compromised, no evidence of chronic scar tissue or inflammation^{5,6}**



ANGIO-SEAL® STS Plus

RELY ON
DUAL SECURITY

The bioabsorbable ANGIO-SEAL anchor + collagen provides dual security, ensuring it is positioned correctly and stays in place^{1,2}

- **Bioabsorbable Anchor**
Designed to fit closely against the arterial wall, leaving blood flow undisturbed with no residual stenosis⁵
- **Bioabsorbable Collagen**
Designed to conform to the arteriotomy for confident closure²
- **Bioabsorbable Suture**
Tethers the anchor and collagen together, providing a secure seal²



ANGIO-SEAL® VIP

ANGIO-SEAL® Evolution™

PERFORM RESTICK
WITH CONFIDENCE

Clinical data supports the safety of restick following an initial ANGIO-SEAL deployment⁷

- Restick can be performed without device dislodgement or any significant vascular complications
- Arterial closure can be achieved with a second ANGIO-SEAL Vascular Closure Device

Vascular Complications Following Restick

COMPLICATIONS		PROPORTION	95% CONFIDENCE INTERVAL
Large Hematoma (≥ 10cm)	3	0.0166	0.0043 – 0.0515
Vessel Occlusion	0	0	0 – 0.0259
Pseudoaneurysm	0	0	0 – 0.0259
AV Fistulae	0	0	0 – 0.0259
Major Bleeding	0	0	0 – 0.0259
Vascular Repair	0	0	0 – 0.0259
Death	0	0	0 – 0.0259

A clinical study of 181 patients evaluated safety and efficacy of a restick of the same artery following an initial ANGIO-SEAL device deployment. Patients were included in the study if they had an ANGIO-SEAL device deployment and subsequently underwent arterial access using the same artery that had previously been closed with an ANGIO-SEAL device within 90 days of the original device placement.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 664635****Issued To:**

**Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA**

In respect of:

Design, development and manufacture of sterile vascular closure devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-01-20**

Date: **2019-07-18**

Expiry Date: **2022-01-19**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 664635**
 Date: **2019-07-18**
 Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

Subcontractor:

Service(s) supplied

DSM Biomedical
 735 Pennsylvania Drive
 Exton
 PA 19341
 USA

Animal Tissues / Derivatives

St. Jude Medical
 14901 DeVeau Place
 Minnetonka
 Minnesota
 55345-2126
 USA

Manufacture

St. Jude Medical Costa Rica Ltda.
 Edificio #44, Calle 0, Ave. 2
 Zona Franca
 El Coyal, Alajuela
 Costa Rica

Manufacture

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265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

Subcontractor:

Service(s) supplied

Sterigenics US, LLC
 1700 College Boulevard
 West Memphis
 AR 72301
 USA

Gamma Sterilization

Sterigenics US, LLC
 1003 Lakeside Drive
 Gurnee
 Illinois
 60031
 USA

Gamma Sterilization

Synergy Health AST SRL
 B13.1 Street 4, Avenue 1
 El Coyo Free Zone
 20102 El Coyo
 Alajuela
 Costa Rica

ETO Sterilization

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Somerset
New Jersey
08873
USA

Subcontractor:

Service(s) supplied

Terumo Europe, N.V.
 Interleuvenlann 40, B-3001
 Leuven
 Belgium

EU Representative

Terumo Puerto Rico LLC
 Innovation Street Lot 21
 Caguas West Industrial Park
 Caguas
 00725
 Puerto Rico

Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 664635**
Date: **2019-07-18**
Issued To: **Terumo Medical Corporation**
265 Davidson Avenue, Suite 320
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Date	Reference Number	Action
20 January 2017	8645594	First issue.
20 October 2017	8794520	Update name and address of subcontractor Terumo Puerto Rico LLC.
27 February 2019	8798156	Traceable to NB 0086.
Current	9659326	Change in legal manufacturer address Updated address of Terumo Puerto Rico LLC to align with BSI ISO certificates.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset
New Jersey
08873
USA

DUNS Number: 96-252-0628

Holds Certificate No:

MDSAP 695791

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Manufacture and Distribution of Sterile Vascular Closure Devices



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-03-03

Effective Date: 2020-03-03

Expiry Date: 2023-03-02



BSI Group America Inc. is an MDSAP authorized auditing organization

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