Angio-Seal®

Vascular Closure Device

THE INSIDE ADVANTAGE™

Bioabsorbable + Dual Security

TERUMO
INTERVENTIONAL SYSTEMS

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**.

TERUMO
INTERVENTIONAL
SYSTEMS

Angio-Seal®
Vascular Closure Device

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 success[3]

  97.8% hemostasis by device[3]

- **The anchor and seal are bioabsorbed:**
  - Fibrin coats the anchor within hours and becomes totally encapsulated in 7-14 days[4]
  - Anchor begins to hydrate and soften 24-36 hours after deployment[4]
  - Anchor is absorbed 95% at 42 days[5]
  - 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]

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 stenosis[5]
- **Bioabsorbable Collagen**
  Designed to conform to the arteriotomy for confident closure[2]
- **Bioabsorbable Suture**
  Tethers the anchor and collagen together, providing a secure seal[2]

ANGIO-SEAL® VIP

ANGIO-SEAL® Evolution™

PERFORM RESTICK WITH CONFIDENCE

Clinical data supports the safety of restick following an initial ANGIO-SEAL deployment[7]

- 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.

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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

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 terumois.com Fax: 800.411.5870

Indications

The Angio-Seal Vascular Closure Device product family, including the 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 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.

TERUMO INTERVENTIONAL SYSTEMS

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 664636**

Issued To: **Terumo Medical Corporation**
2101 Cottontail Lane
Somerset
New Jersey
08873
USA

In respect of:

Angio-Seal Vascular Closure Devices

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **20 January 2017** Date: **20 January 2017** Expiry Date: **19 January 2022**

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EC Design-Examination Certificate

Supplementary Information to CE 664636

Issued To:

Terumo Medical Corporation
2101 Cottontail Lane
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USA

Angio-Seal Vascular Closure Device

Model Number	Description
610120	6F Angio-Seal STS-Plus
610122	8F Angio-Seal STS-Plus
610132	6F Angio-Seal VIP
610133	8F Angio-Seal VIP
C610136	6F Angio-Seal Evolution
C610137	8F Angio-Seal Evolution

First Issued: **20 January 2017** Date: **20 January 2017** Expiry Date: **19 January 2022**

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Supplementary Information to CE 664636

Issued To:

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2101 Cottontail Lane
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08873
USA

Certificate History

Date	Reference Number	Action
20 January 2017	10167452	First Issue.

First Issued: **20 January 2017** Date: **20 January 2017** Expiry Date: **19 January 2022**

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TMC - Declaration of Conformity

Terumo Medical Corporation (TMC) hereby declares that the following TMC facilities and products are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 and Annex II.4 under the supervision of BSI as Notified Body. All supporting documentation is retained under the premises of TMC. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer.

Legal Manufacturer Address:	Terumo Medical Corporation 2101 Cottontail Lane, Somerset, NJ 08873 USA
European Representative:	Terumo Europe, N.V. Interleuvenlaan 40, 3001 Leuven, Belgium
Product Type:	Vascular Closure Device
Product Name(s) and Model Number(s):	**Angio-Seal STS Plus Vascular Closure Device** (610120, 610122) **Angio-Seal VIP Vascular Closure Device** (610132, 610133) **Angio-Seal Evolution Vascular Closure Device** (C610136, C610137)
Classification:	Class III per Annex IX of the MDD 93/42/EEC, Rules 8 and 17
GMDN Code(s):	60710 - Femoral artery compression plug, collagen
EC Certificate No and Expiration Date:	Certificate Annex II No: CE 664635 (Expiration: 19 January 2022) Certificate Annex II.4 No: CE 664636 (Expiration: 19 January 2022)
Applicable Quality System Standards:	ISO 13485: 2003
Notified Body:	BSI, Kitemark Court, Davy Avenue, Knowlhill Milton Keynes MK5 8PP United Kingdom
Notified Body Number:	0086

Signature:

Kathleen Little
VP of Quality and Regulatory Affairs

Issue Date:

20 JAN 2017
Issue Date