Angio-Seal®
VIP

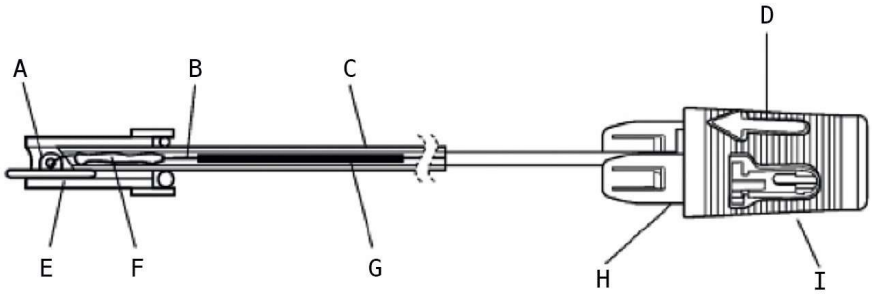
Vascular Closure Device

Angio-seal is a medical device indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic angiography procedures or interventional procedures (minimal artery diameter of 4mm). The 6F Angio-Seal device is for closure after usage of a 6 French or smaller procedural sheath, while the 8F Angio-Seal device is for closure after usage of an 8 French or smaller procedural sheath.

Product Characteristics

- *Insertion Sheath*
- *Arteriotomy Locator*
- *6F (2.0 mm) – 0.035 in. (0.89 mm) Guidewire with J-Straightener or 8F (2.7 mm) – 0.038 in. (0.96 mm) Guidewire with J-Straightener*
- *Angio-Seal consists of 3 bioabsorbable components: anchor, collagen, and suture*
- *10 units per box*
- *Single use, one year shelf life after sterilization*
- *Sterilized by gamma radiation. Do not re-sterilize*
- *Available in select markets*

Storage, packaging and disposal:
- *Should be stored in a cool location (between 15°C and 25 °C)*
- *Contains resorbable materials that degrade by exposure to heat and moisture; therefore, the device may not be resterilized*
- *Sterile and non-pyrogenic in unopened and undamaged package*
- *Dispose of contaminated units, components, and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.*



A Anchor
B Suture
C Carrier tube
D Reference indicator
E Bypass tube
F Hemostatic collagen sponge
G Tamper tube
H Device sleeve
I Device cap

General specifications

Item specifications

Size	Guidewire Diameter	Code
6 Fr	0.035 in	610132
8 Fr	0.038 in	610133

Unit per box: 5 pcs.

Please quote above item reference codes when placing an order

IS803/85GB012IKAVI

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

January 21, 2022

To whom it may concern

RE: Notification of CE mark status for Angio-Seal™ and FemoSeal™

Dear Valued Customer,

The Angio-Seal and/or FemoSeal vascular closure devices (collectively, the "VCD Products") that your Institution currently purchases from Datacontrol bear a CE mark for compliance with the Medical Device Directive 93/42/EEC ("MDD") that was issued to Terumo Medical Corporation ("TMC"), the legal manufacturer, by British Standards Institute ("BSI") of Netherlands.

Unfortunately, TMC will experience a short-term lapse in the VCD Product's CE Mark as we navigate the remaining process steps to achieve Medical Device Regulation (EU) 2017/745 ("EU MDR") CE mark certification from the National Standards Authority of Ireland ("NSAI"). The Technical Documents required for EU MDR CE mark certification for the VCD Products are currently under active review by NSAI.

To ensure that your Institution continues to receive VCD Products during TMC's EU MDR CE mark certification process, you will continue to receive CE marked VCD Products that were manufactured and placed on the EU market prior to the expiry of the current CE mark certificate.

Please be assured that patient safety and health are our number one priority. We greatly appreciate your support as we navigate this transition from the MDD to the EU MDR with these industry established VCD Products.

If you have any questions, please contact Terumo Medical Corporation, Terumo Europe N.V., or Datacontrol.

Sincerely,

John D. Boselli
Sr. Vice President, Quality Management & Regulatory Affairs
Terumo Medical Corporation

Fien Aerts
Vice President, Regulatory & Vigilance
Authorized Representative
Terumo Europe N.V.

By Royal Charter

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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

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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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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 Coyol, Alajuela Costa Rica	**Manufacture**

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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 Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**

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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
Somerset
New Jersey
08873
USA

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.