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 265 Davidson Ave, Suite 320, 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):	**FemoSeal Vascular Closure System** (C11202)
Classification:	Class III per Annex IX of the MDD 93/42/EEC, Rule 8
GMDN Code(s):	58871 - Femoral artery compression plug, synthetic polymer
EC Certificate No and Expiration Date:	Certificate Annex II No: CE 664635 (Expiration: 19 January 2022) Certificate Annex II.4 No: CE 664637 (Expiration: 19 January 2022)
Applicable Quality System Standards:	ISO 13485:2016 / EN ISO 13485:2016
Notified Body:	BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands P.O. Box 74103, 1070 BC Amsterdam, The Netherlands
Notified Body Number:	2797

Signature:

John Boselli
Sr. VP of Quality and Regulatory Affairs

Issue Date:

8/20/2019
Issue Date

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

...making excellence a habit.™

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.

FemoSeal™

Vascular Closure System

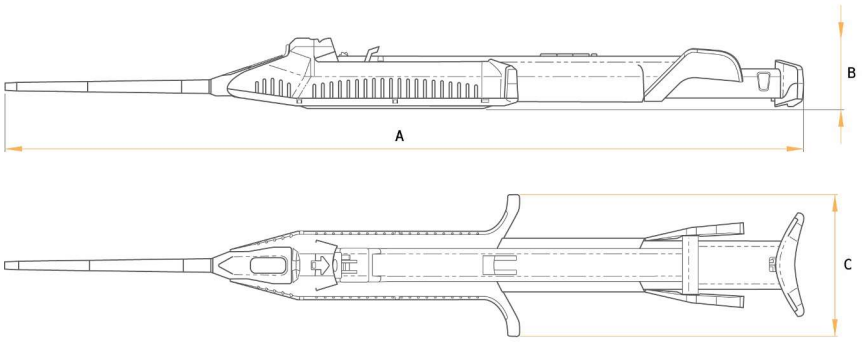
FemoSeal is a medical device indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic or interventional procedures with 7F (2,33 mm) procedural sheath or smaller (minimal artery diameter of 5 mm).

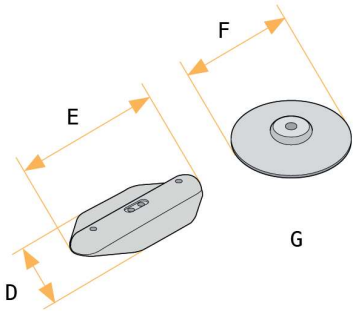
Product Characteristics

- *FemoSeal consists of two fully bioabsorbable polymer discs held together by bioabsorbable sutures. Hemostasis is achieved by mechanically sealing the arteriotomy between the two discs*
- *Single use, one year shelf life after sterilization*
- *Sterilized by ethylene oxide. Do not re-sterilize*
- *Available in select markets*
- *10 units per box*

Storage, packaging and disposal:

- *FemoSeal should be stored in a cool location (room temperature not exceeding 25 °C)*
- *FemoSeal contains resorbable materials that degrade by exposure to heat and moisture; therefore, the device may not be resterilized*
- *FemoSeal is 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 282 mm
B 25 mm
C 50 mm
D 5 mm
E 10 mm
F 5 mm
G 1 mm thick

General specifications

Effective Length Sheath	70 mm
French Size	7 Fr
Guidewire - Diameter	0.038 in / 0.97 mm

Ordering information

C11202

Please quote above item reference codes when placing an order

Unit per box: 10 pcs.

Please quote above item reference codes when placing an order

IS803/12GB0120KAVII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TERUMO MEDICAL CORPORATION
F.C.P.C. DATACONTROL S.R.L.
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08-10-2019
Содержит([NameMake], 'FEMOSEAL')