FemoSeal™

Vascular Closure System

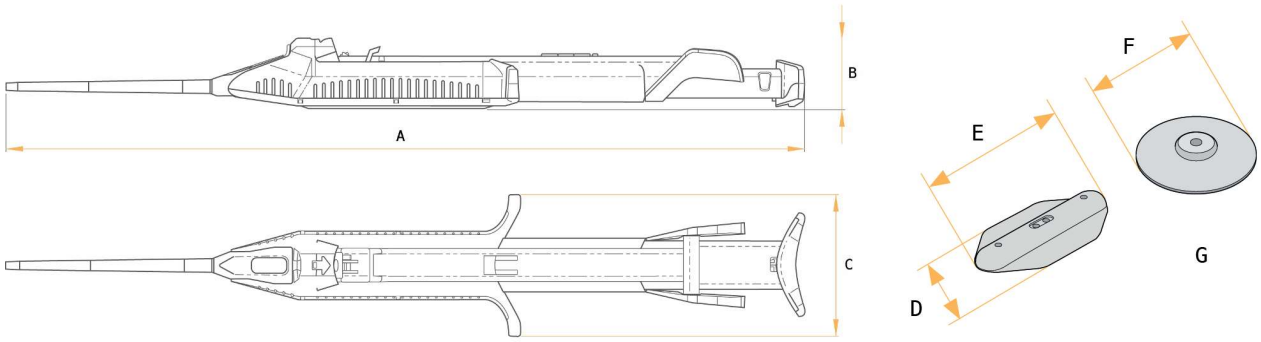
FemoSeal is a medical device indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have undergone diagnostic or interventional procedures with 7F (2,33 mm) procedural sheath or smaller (minimal artery diameter of 5 mm).

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

Digitally signed by Grabazei Alexandru
Date: 2022.01.10 11:00:14 EET
Reason: MoldSign Signature
Location: Moldova

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

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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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EC Certificate - Full Quality Assurance System

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

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Issued To:	**Terumo Medical Corporation** **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 Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

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Date:	**2019-07-18**
Issued To:	**Terumo Medical Corporation** **265 Davidson Avenue, Suite 320** **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
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.