Eliminate™

Aspiration Catheter

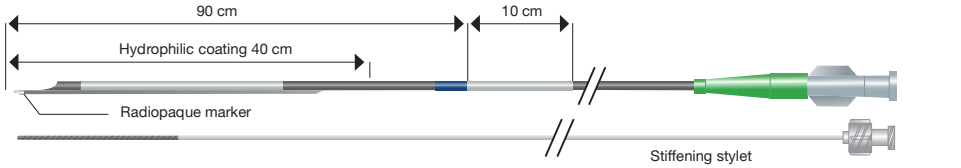
Eliminate is an innovative aspiration catheter designed to offer an optimal balance between crossing performance, kink resistance and thrombus aspiration capability.

Product Characteristics

Dedicated tip design with radiopaque marker
- *To improve crossability, while providing atraumatic and efficient aspiration*
- *To ensure excellent fluoroscopic visibility*

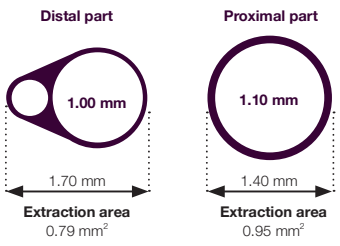
Braided shaft with hydrophilic coating and pre-loaded stiffening stylet (only 6 Fr and 7 Fr are pre-loaded)
- *For an improved pushability and kink resistance*
- *For easy navigation through tortuous anatomies*

Large aspiration lumen
- *For constant, high-performance aspiration throughout the procedure*
- *A choice of 3 sizes (6 Fr, 7 Fr and 8 Fr guide catheter compatibility) for different coronary and peripheral applications*

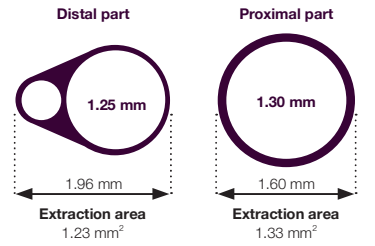


Locking syringes 30 ml | Extension line with 2-way stopcock | Flushing tool | Filter basket

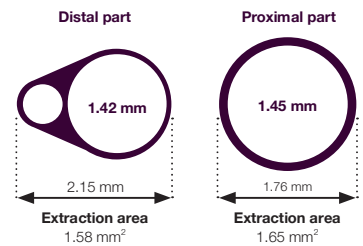
6 Fr guide catheter compatibility



7 Fr guide catheter compatibility



8 Fr guide catheter compatibility



General Specifications

Usable length	140 cm
Distal tip hole length	4 mm for 6 and 7 Fr, 7 mm for 8 Fr
Rapid exchange segment	23 cm
Radiopaque marker	1 mm located at 4 mm from the tip
Positioning marker	10 cm = single white mark located at 90 cm from distal tip
Guide wire compatibility	Maximum diameter 0.014" (0.36 mm)
Coating	Hydrophilic

Item Specifications

Guide catheter compatibility		Guide sheath compatibility	Eliminate
6 Fr	I.D. ≥ 0.070" / 1.78 mm	-	EG1602
7 Fr	I.D. ≥ 0.080" / 2.03 mm	-	EG1652
8 Fr	I.D. ≥ 0.086" / 2.18 mm	6 Fr	EG1401

Please quote above item reference code when placing an order

IS616/22GB0616ITI

CS-DEC-107 Ver.10

TERUMO

DECLARATION OF CONFORMITY

Medical devices

We hereby declare that the distributed CE marked products, specified below, conform to the type(s) covered by the EC Design-Examination Certificate, reference number: 2125694DE01, issued on 9 July 2018 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices as last amended by 2007/47/EC.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class III under Rule 6 of Annex IX in the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive, and is described in the CE Marking of Conformity Certificate, reference number: 2125694CE01, issued on 9 July 2018 and delivered by DEKRA Certification B.V..

This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485, Quality System Certificate with reference number: 2125269 issued on 5 June 2018 and delivered by DEKRA Certification B.V..

This Declaration of Conformity covers thrombectomy catheter as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Manufacture: TERUMO CLINICAL SUPPLY Co., Ltd.
3, Kawashima-Takehayamachi, Kakamigahara,
Gifu, 501-6024, Japan

EU Representative is; TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Date of issue 9 July 2018

Signature: Koji Date: 9 July 2018

Koji Iida
General Manager of Quality Assurance Department,
TERUMO CLINICAL SUPPLY Co., Ltd.

Annex: Product list (CS-DEC-107-List Ver.10)

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:38:20 EEST
Reason: MoldSign Signature
Location: Moldova

TERUMO

PRODUCT LIST

Product name: ELIMINATE
(Aspiration Catheter)

This product list belongs to the Declaration of Conformity identified by CS-DEC-107 Ver.10 and specifies the CE marked products concerned that TERUMO CLINICAL SUPPLY Co., Ltd. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as last amended by 2007/47/EC. The following list identifies the products by code number and by type name.

Code Number	Type Name	Date of CE Marking
EG1401	ELT8FGC-140-RX	November 18, 2009
EG1402	ELT8FGC-140-MRX-ST	November 18, 2009
EG1403	ELT8FGC-125-MRX-ST	November 18, 2009
EG1502	ELT2-6FGC-140-RX-ST	November 18, 2009
EG1552	ELT2-7FGC-140-RX-ST	November 18, 2009
EG1602	ELT3-6FGC-140-RX-ST	November 18, 2009
EG1652	ELT3-7FGC-140-RX-ST	November 18, 2009

Date of issue 9 July 2018

Signature: Koji Date: 9 July 2018

Koji Iida
General Manager of Quality Assurance Department,
TERUMO CLINICAL SUPPLY Co., Ltd.

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2125694DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
TERUMO CLINICAL SUPPLY CO., LTD.
3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

For the product

Thrombectomy catheters: type aspiration catheters: Extractor and Eliminate catheters

Documents, that form the basis of this certificate:

Certification Notice 2125694CN, initially dated 28 October 2009
CE Marking of Conformity 2125694CE01
Addendum, initially dated 9 July 2018

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 9 July 2023
Issued for the first time: 28 October 2009
Reissued: 9 July 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2125694DE01

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Thrombectomy catheters: type aspiration catheters: Extractor and Eliminate catheters

Issued to:

TERUMO CLINICAL SUPPLY CO., LTD.
3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

This certificate covers the following product(s):

Type No.	ELIMINATE Code No.	Extractor Code No.
ELT8FGC-140-RX	EG1401	
ELT8FGC-140-MRX-ST	EG1402	
ELT8FGC-125-MRX-ST	EG1403	
ELT2-6FGC-140-RX-ST	EG1502	CG1502
ELT2-7FGC-140-RX-ST	EG1552	CG1552
ELT3-6FGC-140-RX-ST	EG1602	CG1602
ELT3-7FGC-140-RX-ST	EG1652	CG1652

Initial date: 9 July 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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CERTIFICATE

Number: 2125269

The management system of:

TERUMO CLINICAL SUPPLY CO., LTD.

3 Kawashima-Takehayamachi Kakamigahara
Gifu 501-6024
Japan

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:
Design, development and manufacture of catheters, guide-wires, sheath Introducers, vascular access ports, and medical tubing for use in the area of interventional radiology and interventional cardiology.

Certificate expiry date: 1 June 2024
Certificate effective date: 1 June 2021
Certified since: 12 May 2009

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

EC CERTIFICATE

Number: 2125694CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

TERUMO CLINICAL SUPPLY CO., LTD.

3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

For the product category(ies)

Intravascular catheters

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2125694CN, initially dated 28 October 2009
Addendum, initially dated 28 October 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 9 July 2023
Issued for the first time: 28 October 2009
Reissued: 9 July 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2125694CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Intravascular catheters

Issued to:

TERUMO CLINICAL SUPPLY CO., LTD.
3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

This certificate covers the following product(s):

Thrombectomy Catheters: Extractor and Eliminate

Initial date: 28 October 2009
Revision date: 11 April 2014

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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