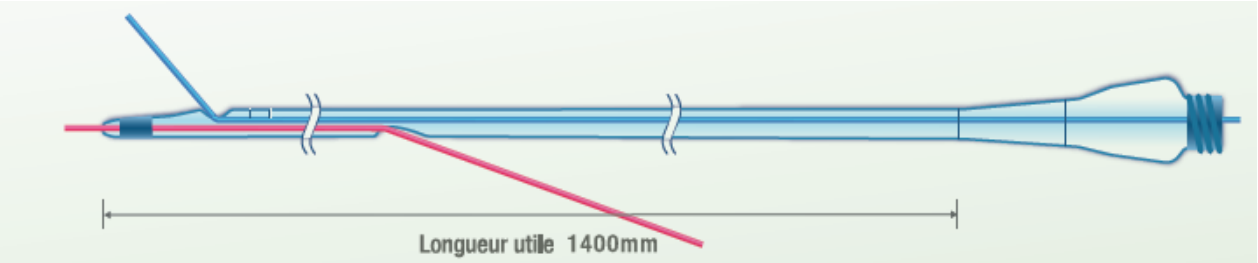
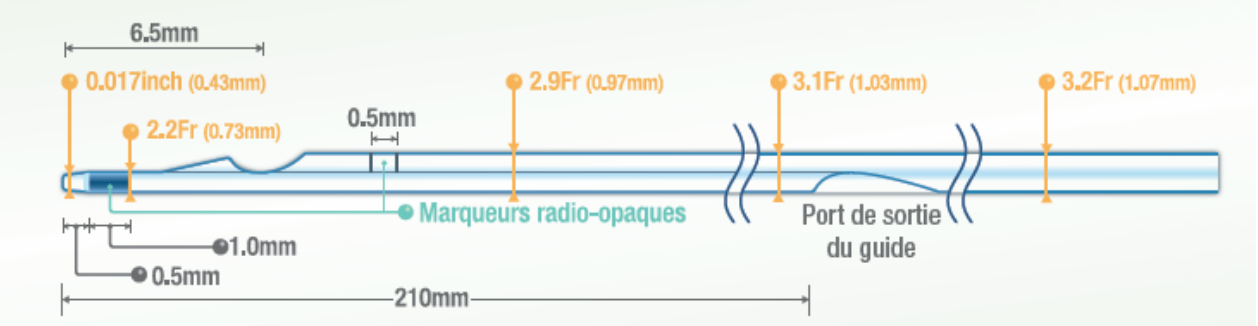
Fiche Technique: FineDuo®

Descriptif du dispositif :

Le FineDuo est un micro-cathéter multifonction à deux lumières pour l'accès aux branches filles, particulièrement utile pour la manipulation du guide lors des interventions de stenting de bifurcation.



Spécifications :



Référence	NC-D724
Diamètre interne minimum du cathéter guide compatible	0.056" (1.44 mm)
Diamètre maximum du guide compatible	0.014" (0.36mm)
Longueur utile	1400 mm

FineDuo® est exclusivement réservé aux professionnels de santé.
FineDuo® est destiné à être utilisé pour soutenir le guide dans le franchissement de la branche latérale et l'échange de guides au cours de l'angioplastie coronaire transluminale percutanée.
Se reporter aux instructions figurant sur le manuel d'utilisation.
Dispositif médical de classe III (TÜV Rheinland CE n°0197), non pris en charge par l'assurance maladie.

Terumo France S.A.S.
Bâtiment Renaissance
3 rond-point des Saules
78280 Guyancourt
Tel : 01 30 96 13 00
Fax : 01 30 43 60 85

Fabricant:
Kaneka Corporatio n
3-2-4, Nakanoshima, Kita-ku
Osaka 530-8288
Japon

Fiche Technique: Glidesheath Slender®

Descriptif du dispositif :

Le GlideSheath Slender® est un kit qui comprend un introducteur (une gaine et un dilatateur), un mini guide métallique ou plastique et une aiguille de ponction. Il est conçu pour les procédures par voie radiale.

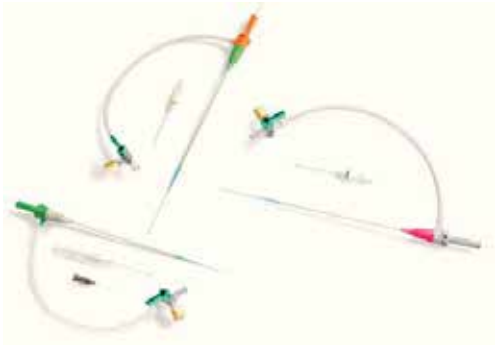
La gaine est recouverte du revêtement hydrophile M Coat™.

Le concept unique du Glidesheath Slender permet d'offrir une gaine d'un diamètre externe réduit de 1 Fr grâce à une gaine ultrafine. Le Glidesheath Slender est disponible en taille 5 Fr, 6 Fr et 7 Fr.

Kits et tailles disponibles :

Gaine de l'introducteur		Aiguille de ponction		Mini-guide	
5 Fr 6 Fr 7 Fr	10 cm 16 cm	Surflash®	20G 22G	Plastique droit / angulé Métallique	0.021'' 0.025''
		En métal	20G 21G 22G [1]	Métallique	0.018'' [2] 0,021" 0,025"

[1] disponible uniquement dans les kits 5 et 6Fr
[2] disponible uniquement dans les kits 5 et 6Fr de longueur 10cm



Glidesheath Slender® est exclusivement réservé aux professionnels de santé.
Glidesheath Slender® sert à faciliter l'introduction sous-cutanée d'un cathéter dans l'artère radiale.
Classe du dispositif médical : IIa (CE TUV 0197)
Se reporter aux instructions figurant dans le manuel d'utilisation.

Terumo France S.A.S.
Bâtiment Renaissance
3 rond-point des Saules
78280 Guyancourt
Tel : 01 30 96 13 00
Fax : 01 30 43 60 85

Fabricant:
Terumo Corporation
44-1,2 Chome, Hatagaya
Shibuya-ku
Tokyo 151-0072
Japon

Fiche Technique: Ultimaster®

Descriptif du dispositif :

Le stent Ultimaster® est une endoprothèse coronaire à libération de Sirolimus à partir d'un polymère dégradable. Sa plateforme est en cobalt-chrome (CoCr) L605 et possède un revêtement abluminal constitué d'une matrice dérivée de l'acide polylactique (Poly-D,L-lactide-co-caprolactone) contenant le Sirolimus. Il est serti sur le ballonnet d'un cathéter d'angioplastie coronaire à échange rapide.

Le stent coronaire au CoCr Kaname™, plate-forme de l'Ultimaster®, est un stent flexible à mailles fines (80µm) et à cellules ouvertes, offrant une délivrabilité et un accès aux ramifications secondaires.

L'Ultimaster®, stent coronaire à libération de sirolimus est doté d'un revêtement constitué de deux couches: une couche primaire et une couche de matrice médicamenteuse. La couche primaire et le polymère de support du médicament, copolymère poly(D,L-lactide-co-caprolactone) doivent se dégrader en l'espace de 3-4 mois. Le revêtement médicamenteux est appliqué de façon abluminale, ce qui signifie que la face luminale du stent est dépourvue de médicament.

Tailles disponibles :

Longueurs (mm)	9 / 12 / 15 / 18 / 24 / 28 / 33 / 38
Diamètres (mm)	2.25 / 2.50 / 2.75 / 3.00 / 3.50 / 4.00

Ultimaster® est exclusivement réservé aux professionnels de santé.
L'Ultimaster®, stent coronaire à libération de sirolimus est indiqué pour améliorer la perfusion au niveau du myocarde chez les patients atteints de lésions sténotiques des artères coronaires.
Se reporter aux instructions figurant dans le manuel d'utilisation.
Dispositif médical de classe III (CE 0482 MedCert)

Fait l'objet d'une prise en charge au titre de la liste des Produits et Prestations Remboursables (LPPR) prévue par l'article L165-1 du code de la sécurité sociale, pour les diamètres de 2.25 à 4.0 mm et les longueurs de 9 à 38 mm.

Terumo France S.A.S.
Bâtiment Renaissance
3 rond-point des Saules
78280 Guyancourt
Tel : 01 30 96 13 00
Fax : 01 30 43 60 85

Fabricant:
Terumo Europe N.V.
Interleuvenlaan 40
3001 Louvain
Belgique

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTI

Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 17 04 24736 060

Manufacturer:
KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku
Osaka-city, OSAKA
530-8288 JAPAN

EC-Representative:
KANEKA PHARMA EUROPE N.V.
Nijverheidsstraat 16
2260 Westerlo-Oevel
BELGIUM

Product Category(ies):
Suction Catheter Set, Catheter for Angioplasty and Balloon Dilation Catheter for Angioplasty

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JNQ235029570**

Valid from: **2017-08-17**
Valid until: **2022-01-21**

Date, **2017-08-17**

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

Product Service

EC Certificate
Full Quality Assurance System

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

No. G1 17 04 24736 060

Facility(ies):

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN

KANEKA Corporation Osaka Plant
5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN

KANEKA Medix Corporation Kanagawa Plant
225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

KANEKA PHARMA VIETNAM CO., LTD.
35 VSIP Street 6, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, VIETNAM

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 04 24736 065

Holder of Certificate: **KANEKA Corporation**
3-18, 2-Chome, Nakanoshima, Kita-ku
Osaka-city, OSAKA
530-8288 JAPAN

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Medical Device for Selective Plasma Component Adsorption, Medical Device for Blood Purification, Neuro Surgical Products, Catheters for Interventional Radiology, Surgical Products, Sillicone Tubing Ophthalmic Products, Cell Separation Device
Design and Development and Distribution of Plasma Separator, Blood Tubing Lines, Apheresis Unit
Distribution of Blood Flowmeter

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: **JNQ235029570**

Valid from: **2017-09-01**
Valid until: **2020-08-31**

Date, 2017-08-17

Stefan Preiß

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE
No. Q5 17 04 24736 065

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN

KANEKA Corporation Osaka Plant
5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN

KANEKA Medix Corporation Kanagawa Plant
225-1, Aza Deguchi, Yamakita, Yamakita-machi, Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

KANEKA Medix Corporation Osaka Office
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN

KANEKA PHARMA VIETNAM CO., LTD.
35 VSIP Street 6, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, VIETNAM

KANEKA Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

KANEKA Medix Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

KANEKA Medix Corporation Tokyo Logistics Center
1-4-3, Katsu-shima, Shinagawa-ku, Tokyo, 140-0012 JAPAN

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TÜV®

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Product Service

EC Certificate

EC Design-Examination Certificate

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

No. G7 18 05 24736 068

Manufacturer:

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku
Osaka-city, OSAKA
530-8288 JAPAN

EC-Representative:

KANEKA PHARMA EUROPE N.V.
Nijverheidsstraat 16
2260 Westerlo-Oevel
BELGIUM

Product: **Catheters for Single Use**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713121823

Valid from: 2018-06-19
Valid until: 2023-05-21

Date, 2018-06-19

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate
EC Design-Examination Certificate

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

No. G7 18 05 24736 068

Model(s):

Dual Lumen Catheters
- Crusade Catheter KMF0114A
- FineDuo Catheter NC-D724

Parameters:

Effective length 1400 ± 20 mm
Maximum outer diameter 1.07 ± 0.02 mm
For guide wire size 0.014 inch (0.36 mm)
For guide catheter size 0.056 inch (1.44 mm)

Facility(ies):

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,
530-8288 JAPAN

KANEKA Corporation Osaka Plant
5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN

KANEKA Medix Corporation Kanagawa Plant
225-1, Aza Deguchi, Yamakita, Yamakita-machi,
Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

KANEKA PHARMA VIETNAM CO., LTD.
35 VSIP Street 6, Vietnam - Singapore Industrial Park, An Phu
Ward, Thuan An Town, Binh Duong Province, VIETNAM

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 024736 0069 Rev. 02

Holder of Certificate: KANEKA

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku
Osaka-city, OSAKA
530-8288 JAPAN

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of Medical Device for Selective Blood or Plasma Component Adsorption, Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation / Harvesting, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology.
Production and Distribution of Blood Flowmeter and Inflation Device.
Distribution of Plasma Separator, Blood Tubing Lines and Apheresis Unit.
Design and Development, Production and Distribution of In-vitro Diagnostic Products for Genetic-testing.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 024736 0069 Rev. 02

Report No.: **JN1459484**

Valid from: **2021-03-01**
Valid until: **2023-08-31**

Date, **2021-02-10**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 024736 0069 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

KANEKA Corporation
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA, 530-8288 JAPAN

Design and Development, Production and Distribution of Medical Devices for Selective Blood or Plasma Component Adsorption, Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation / Harvesting, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology
Production and Distribution of Blood Flowmeter and Inflation Device
Distribution of Plasma Separator, Blood Tubing Lines and Apheresis Unit
Design and Development, Production and Distribution of In-vitro Diagnostic Products for Genetic-testing

KANEKA Corporation Osaka Plant
5-1-1, Torikai-Nishi, Settsu-city, OSAKA, 566-0072 JAPAN

Design and Development, Production and Distribution of Medical Devices for Selective Blood or Plasma Component Adsorption, Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Cell Separation / Harvesting, Endoscopic Intervention, Ophthalmology and Vascular / Neurovascular Embolization
Production and Distribution of Blood Flowmeter and Inflation Device
Distribution of Plasma Separator, Blood Tubing Lines and Apheresis Unit
Production and Distribution of In-vitro Diagnostic Products for genetic-testing

KANEKA Corporation Takasago Plant
1-8, Miyamae-cho, Takasago-cho, Takasago, Hyogo, 676-8688 JAPAN

Design and Development, Production and Distribution of In-vitro Diagnostic Products for genetic-testing

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TÜV SÜD Product Service

Certificate

No. Q5 024736 0069 Rev. 02

Facility(ies):

KANEKA Medix Corporation Kanagawa Plant
225-1, Aza Deguchi, Yamakita, Yamakita-machi,
Ashigara-Kami-gun, KANAGAWA, 258-0113 JAPAN

Production and Distribution of Medical Devices for Catheter Intervention, Surgical or Neurosurgical Drainage, Cerebral Shunt, Vacuum Extraction Delivery, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

KANEKA Medix Corporation Osaka Office
3-18, 2-Chome, Nakanoshima, Kita-ku, Osaka-city, OSAKA,
530-8288 JAPAN

Sales Office

KANEKA MEDICAL VIETNAM CO., LTD.
35 VSIP Street 6, Vietnam - Singapore Industrial Park,
An Phu Ward, Thuan An City, Binh Duong Province, VIETNAM

Production of Catheter Intervention, Endoscopic Intervention, Ophthalmology, Vascular / Neurovascular Embolization and Cardiac Electrophysiology

KANEKA Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

KANEKA Medix Corporation Tokyo Office
12-32, 1-Chome, Akasaka, Minato-ku, Tokyo, 107-6028 JAPAN

Sales Office

KANEKA Medix Corporation Tokyo Logistics Center
3-2-52, Yashio, Shinagawa-ku, Tokyo, 140-0003 JAPAN

Distribution of all products

Kaneka Medical Tech Corporation Ina Factory
7108-1 Nishiminowa, Ina-shi, Nagano, 399-4501 JAPAN

Production and Distribution of Medical Devices for Endoscopic Intervention and Ophthalmology

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TÜV SÜD
Product Service

Certificate

No. Q5 024736 0069 Rev. 02

Facility(ies):

Kaneka Medical Tech Corporation Okaya Factory
2-6-16 Kohan, Okaya-shi, Nagano, 394-0034 JAPAN

Design and Development, Production and Distribution of Medical Devices for Endoscopic Intervention, Ophthalmology and Cardiac Electrophysiology

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