COMPANY INTRODUCTION

Invent Bio-med Pvt. Ltd.

Invent Bio-Med a dream project conceived by group of dedicated people to add feather in a cap of India's growing economic boom by inaugurating its state of the art medical device manufacturing facility.

Invent Bio Med is located at Sachin, Near Surat approximately 250 Kilometers from Mumbai, financial capital of India easily approachable by road, rail and air, this area is marked as special economic zone.

Invent Bio-Med has clean room area of three categories viz. Class 100, Class 10,000, Class 100,000.

This world class facility is capable of producing various medical devices and drug coated stents for Interventional Cardiology.

INVENT BIO-MED Pvt. Ltd.
Invention Enhances Life...
An ISO 9001-2008, ISO 13485-2003 Certified Company

INTERVENTIONAL DEVICE DIVISION

QUALITY POLICY.

Our endeavor is to manufacture and market high quality Intravascular Medical Devices of requisite standards by continuously striving to excel with customer focused activities and improving effectiveness of Quality Management System.

MISSION.

Occupy a prominent place in Global Healthcare arena by producing cost effective Intravascular & Critical care devices, that conform to International quality of high standard, with focus on research and strategic collaboration to achieve total customer satisfaction.

CERTIFICATES

EVPÚ

CERTIFICATE

No: 51033/Q/2011

Invent Bio-Med Pvt. Ltd.

109, Surat Special Economic Zone, Diamond Park, G.I.D.C.,
Sachin, Surat, Gujarat - 394230, India

Certification body of management systems
hereby confirms that management system of above-mentioned organization has
been assessed and certified as meeting requirements of

ISO 9001: 2008

for

Design, Development, Manufacturing, Marketing and Distribution
of
Vascular Interventional Devices

Nova Dubnica, August 17th, 2011
The certificate is valid until August 16th, 2014

Marek H u d á k
Head of Certification body

EVPÚ a. s., Trenčianska 19,
018 51 Nová Dubnica, Slovak Republic
www.evpu.sk

SNAS
Reg. No. 010/Q-051

EVPU

NOTIFIED BODY No. 1293

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, as amended by 2007/47/EC of the EP and of the Council of 5th September 2007, Annex II (4) transposed into "Slovak government decree No. 582/2008 Coll. of Laws" as amended

No. 41115/101/1/2011/CE

Manufacturer	Invent Bio-Med Pvt. Ltd. 517, Laxmi Plaza, New link Road, Andheri (W), Mumbai 400053 India
Facility	Invent Bio-Med Pvt. Ltd. 109, Surat Special Economic Zone, Diamond Park, G.I.D.C., Sachin, Surat, Gujarat- 394 230, India
Product(s)	Cardiovascular Medical Device
Product type(s)	Invento Rapid Exchange PTCA Dilatation Catheter
Classification of medical device	Medical Devices – Class III
Final report number	41115/2011/C
Date of issue	November 7th, 2011
Date of the end of validity	November 6th, 2016

Marek Hudák

CE 1293

EVPU

NOTIFIED BODY No. 1293

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

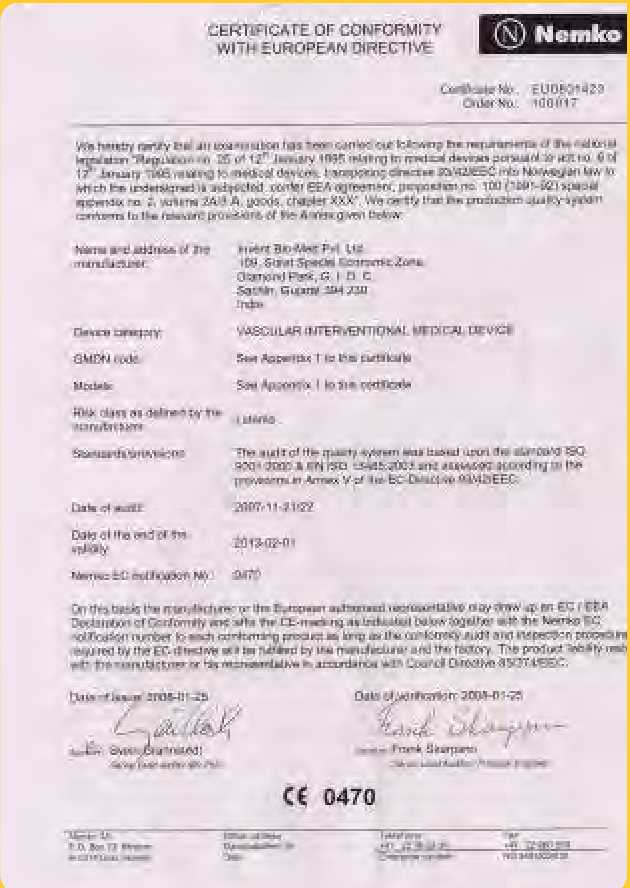
Directive 93/42/EEC on Medical devices, as amended by 2007/47/EC of the EP and of the Council of 5th September 2007, Annex II (with the exemption of section 4) transposed into "Slovak government decree No. 582/2008 Coll. of Laws" as amended

No. 40114/101/1/2011/CE

Manufacturer	Invent Bio-Med Pvt. Ltd. 517, Laxmi Plaza, New link Road, Andheri (W), Mumbai 400053 India
Factory	Invent Bio-Med Pvt. Ltd. 109, Surat Special Economic Zone, Diamond Park, G.I.D.C. Sachin, Surat, Gujarat- 394 230, India
Product(s)	Cardiovascular Medical Device
Product type(s)	Nano-Chrom Co-Cr Coronary Stent Delivery System
Classification of medical device	Medical Devices – Class III
Scope of quality system	Quality of design, production, storage and distribution of Cardiovascular Medical Device
Final report number	40114/2011/C
Date of issue	October 17th, 2011
Date of the end of validity	October 16th, 2016

Marek Hudák

CE 1293



CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0801423
Order No.: 100017

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below.

Name and address of the manufacturer:	Invent Bio-Med Pvt. Ltd. 109, Surat Special Economic Zone, Diamond Park, G. I. D. C. Sachin, Gujarat 394 230 India
Device category:	VASCULAR INTERVENTIONAL MEDICAL DEVICE
GMDN code:	See Appendix 1 to this certificate
Models:	See Appendix 1 to this certificate
Risk class as defined by the manufacturer:	III
Standards/provisions:	The audit of the quality system was based upon the standard ISO 9001:2000 & EN ISO 13485:2003 and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC.
Date of audit:	2007-11-21/22
Date of the end of the validity:	2013-02-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC-directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

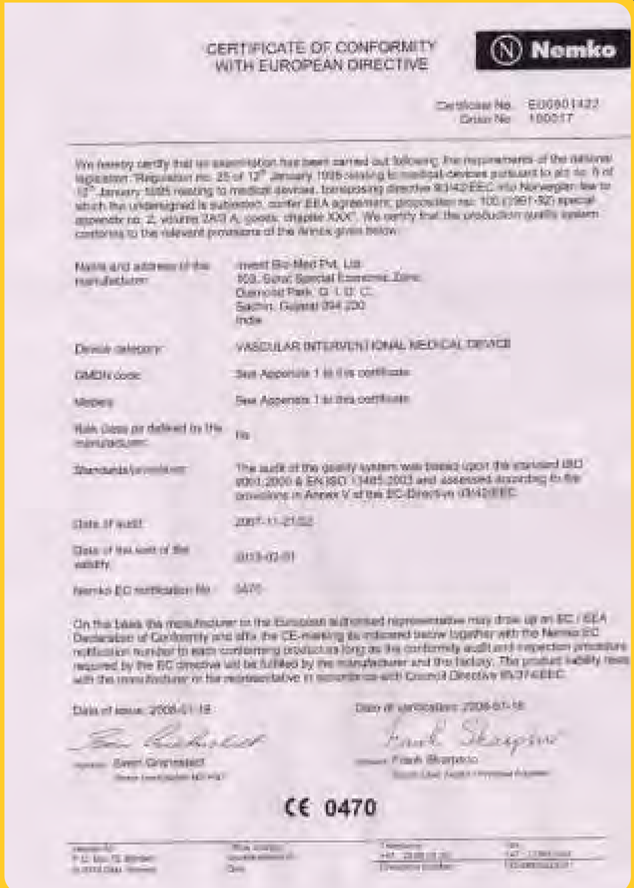
Date of issue: 2008-01-25

Svein Bratnested

Date of verification: 2008-01-25

Frank Skarpeno

CE 0470



CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0801422
Order No.: 100017

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below.

Name and address of the manufacturer:	Invent Bio-Med Pvt. Ltd. 109, Surat Special Economic Zone, Diamond Park, G. I. D. C. Sachin, Gujarat 394 230 India
Device category:	VASCULAR INTERVENTIONAL MEDICAL DEVICE
GMDN code:	See Appendix 1 to this certificate
Models:	See Appendix 1 to this certificate
Risk class as defined by the manufacturer:	IIa
Standards/provisions:	The audit of the quality system was based upon the standard ISO 9001:2000 & EN ISO 13485:2003 and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC.
Date of audit:	2007-11-21/22
Date of the end of the validity:	2013-02-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2008-01-18

Svein Bratnested

Date of verification: 2008-01-18

Frank Skarpeno

CE 0470

Grasp MICROGRAPER

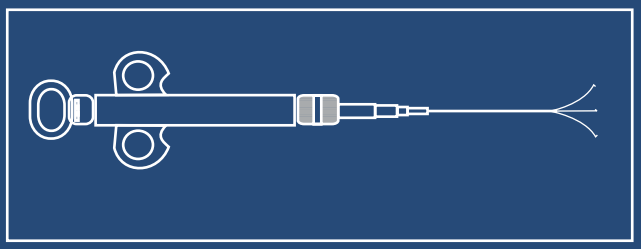
Vascular Retrieval Device

CE 1293

Features

- Radio opaque snare loop 90° to the Shaft.
- Coated by smooth and uniform polyamide tubing
- Sheath- Buffed Tip (Atroumatic Tip)
- Shape memory, super elastic properties , kink resistant.
- Best retrieval of a free particle with thin end by side grap technique

illustration



Ordering Information

Cat Code	Loop Dia/Length	Snare length(cm)	Snare Shaft (cm)	Shaft Size
220101	2 mm / 10 mm	150	140	3F
220102	4 mm / 15 mm	150	140	3F
220103	7 mm / 20 mm	150	140	3F
220104	2 mm / 10 mm	150	140	4F
220105	4 mm / 15 mm	150	140	4F
220106	7 mm / 20 mm	150	140	4F

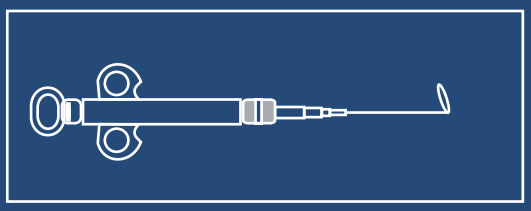
Grasp
MICROSNARE
Vascular Retrieval Device

CE 0470

Features

- Radio Opaque Snare loop, 90º to the shaft
- Shaft Highly Elastic, Flexible, Kink Resistance Nitinol alloy made.
- Coated by smooth and uniform polyamide tubing
- Sheath- Buffed Tip (Atroumatic Tip)
- Snare Nitinol Made
- Wire Stain less steel
- Palm control Plunger poly vinylchloride made.

illustration



Ordering Information

Cat Code	Loop Dia/Length	Snare length(cm)	Snare Shaft (cm)	Shaft Size
110101	2 mm / 10 mm	150	140	3F
110102	4 mm / 15 mm	150	140	3F
110103	7 mm / 20 mm	150	140	3F
110104	2 mm / 10 mm	150	140	4F
110105	4 mm / 15 mm	150	140	4F
110106	7 mm / 20 mm	150	140	4F

Grasp

BASKET

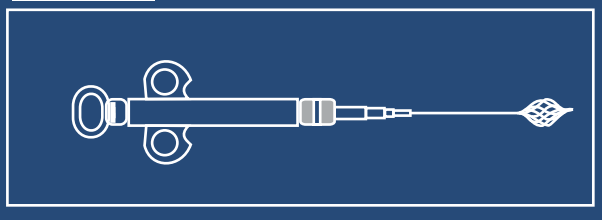
Vascular Retrieval Device

CE
0470

Features

- Radio opaque helical loop Basket 3F/4F.
- Easy manoeuvrability.
- Kink Resistant Shaft.
- Palm & Finger Control Grip.
- Excellent Shape memory.
- Super elastic property of nitinol.
- Sheath- Buffed Tip (Atroumatic Tip)
- Palm control Plunger poly vinylchloride made.

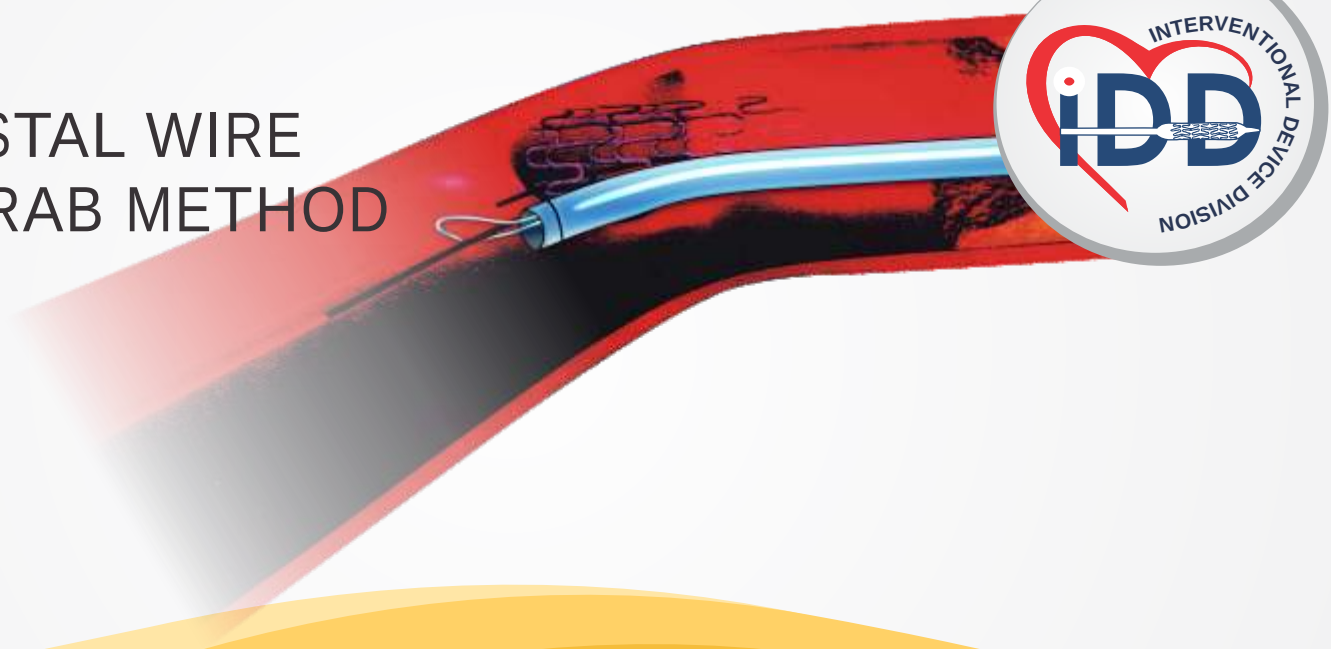
illustration



Ordering Information

Cat Code	Loop Dia/Length	Basket length(cm)	Basket Shaft (cm)	Shaft Size
110201	4 / 20 mm	150	140	3F
110202	6 / 29 mm	150	140	3F
110203	8 / 29 mm	150	140	3F
110204	4 / 20 mm	150	140	4F
110205	6 / 29 mm	150	140	4F
110206	8 / 29 mm	150	140	4F

DISTAL WIRE GRAB METHOD



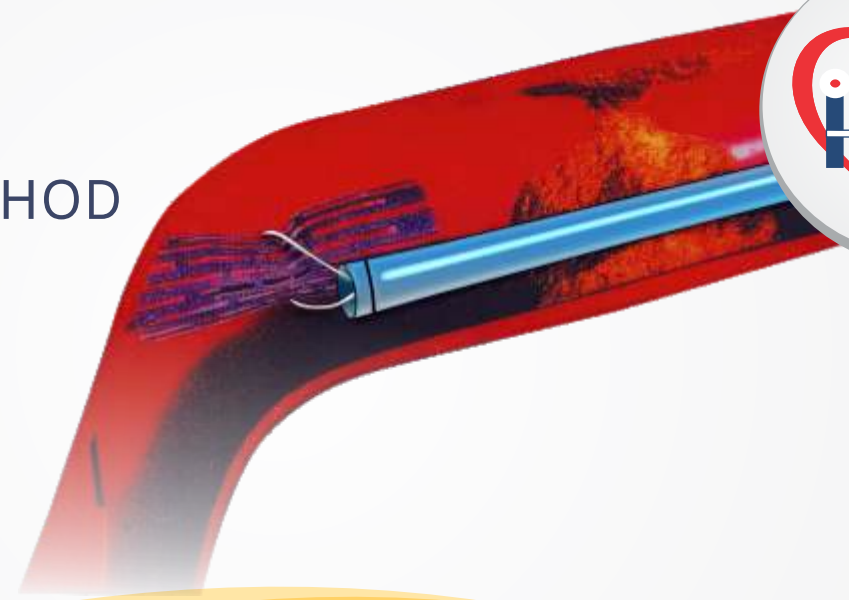
Secondary Method

- Select the appropriate size microsnare for the location in which the stent is located. In general, the microsnare loop should approximate the size of the vessel in which it will be used.
- Assemble the microsnare device, as per “Instructions given”.
- Remove the indwelling balloon or delivery catheter, if present. It may be necessary to change or extend the indwelling guidewire to facilitate balloon removal, and to up-size the indwelling guide catheter/sheath to accommodate the 3 french microsnare catheter.
- Introduce and position a second guidewire adjacent to the stent, and distal to the originally placed guidewire.
- Place the microsnare loop over the proximal end of the second guidewire wire, and clinch until just snug by pulling the proximal end of the microsnare shaft.

Note: Only the loop of the microsnare is placed over the wire.

- Advance the microsnare, distal end first, into the guide catheter or sheath until the distal end of the microcatheter is positioned distal to the stent and the original guidewire.
- Push the microsnare shaft forward gently to completely open the loop, move the microsnare (shaft and microcatheter as a single unit) proximally to snare the distal end of the original indwelling guidewire.
- By advancing the microcatheter, close the loop of the microsnare to grab the original guidewire.
- Maintain tension on the microcatheter and move the microsnare (shaft and microcatheter as one unit) and both guidewires proximally to or into the guide catheter or sheath. The stent is then withdrawn through or together with the guiding catheter in vascular sheath.

PROXIMAL GRAB METHOD



Primary Method

- Select the appropriate size microsnare for the location in which the stent is located. In general, the microsnare loop should approximate the size of the vessel in which it will be used.
- Assemble the microsnare device, as per "Instructions given".
- Remove the indwelling balloon or delivery catheter, if present. It may be necessary to change or extend the indwelling guidewire to facilitate balloon removal, and to size the indwelling guide catheter/sheath to accommodate the 3 french microsnare catheter.
- Place the microsnare loop over the proximal end of the second guidewire and clinch until just snug by pulling the proximal end of the microsnare shaft.

Note: Only the loop of the microsnare is placed over the wire.

- Advance the microsnare, distal end first, into the guide catheter or sheath until the distal end of the microcatheter is positioned distal to the stent and the original guidewire.
- Push the microsnare shaft forward gently to completely open the loop, Move the microsnare (shaft and microcatheter as a single unit) proximally to snare the distal end of the original indwelling guidewire.
- By advancing the microcatheter, the loop of the microsnare is closed to grab the stent.

Note: Attempting to close the loop by pulling the microsnare within the microcatheter will move the loop from its position around the stent

- Maintain tension on the microcatheter and move the microsnare and microcatheter together (proximally) to or into the guide catheter or sheath.The stent is then withdrawn through or together with the guiding catheter in vascular sheath.
- Note: Wire coil stents will likely unravel during retrieval.
- If no guidewire is present, steps three and four may not be appropriate

RADTRANS SET

Features

- Used to reduce vascular access complications
- Excellent flexibility of Nickle-titamium guidewire without kinking
- Smooth atraumatic insertion & removal of uniquely designed sheath
- Kit Includes everything for the applicable procedure

Cat Code	French Size	Length*
111701R	4F	9cm
111702R	5F	11cm
111703R	6F	11cm
111704R	7F	11cm
111705R	4F	18cm
111706R	5F	23cm
111707R	6F	23cm
111708R	7F	23cm

INVENT BIO-MED Pvt. Ltd.
Invention Enhances Life...
An ISO 9001-2008, ISO 13485-2003 Certified Company

INTERVENTIONAL DEVICE DIVISION

Invent Bio-Med Pvt. Ltd. Surat, INDIA

109, Special Economic Zone, Diamond Park,
G.I.D.C., Sachin, Surat,
Gujarat - 394 230,
INDIA.

Tel.: +91-261- 323- 0180
Fax: +91-261- 239- 7157

Email: Info@inventbio-med.com

Invent Bio-Med Pvt. Ltd. Mumbai, INDIA
517, Laxmi Plaza, New Link Road Andheri (W)
Mumbai - 400 053
INDIA.

Tel.: +91-22- 2632- 4234
Fax: +91-22- 2632- 4250

Email: sales@inventbio-med.com

Invent Bio-Med Pvt. Ltd. USA

3301, Moncucco Way, San Jose, CA 95148
USA

Tel.: (408) - 2239977