



## PRODUCT TECHNICAL FORM

**Device name :**

Extraction Basket

**Trade name:**

/

**Description:** The device is divided into Class IIa according to MDR 2017/745

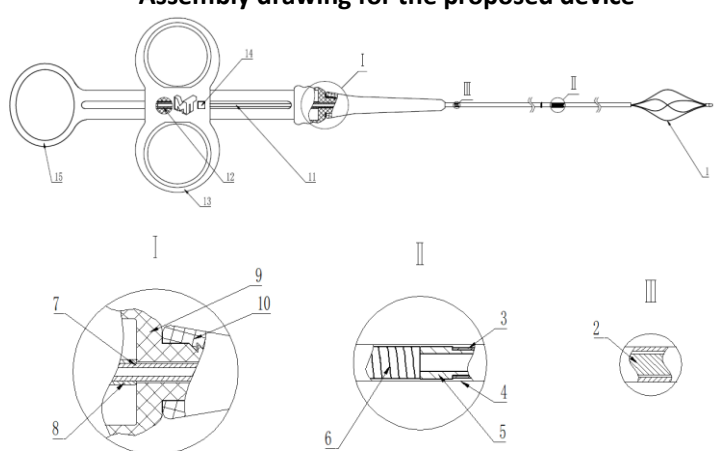


**References:**

CEB00000, CEB01010, CEB02020, CEB03030, CEB04040, CEB00001,  
CEB01011, CEB02021, CEB03031, CEB04041, CEB00002, CEB01012,  
CEB02022, CEB03032, CEB04042, CEB00003, CEB01013, CEB02023,  
CEB03033, CEB04043, CEB00004, CEB01014, CEB02024, CEB03034,  
CEB04044, CEB00005, CEB01015, CEB02025, CEB03035, CEB04045,  
CEB00006, CEB01016, CEB02026, CEB03036, CEB04046

**Intended Use:** This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.

<b>Indication</b>	This device is used for the endoscopic removal of stones in the biliary system and foreign bodies.
<b>Security of use</b>	<p>1) For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in inpatient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, reprocessed or resterilized.</p> <p>2) This device shall not be used for any purpose other than its intended use.</p> <p>3) Make sure the endoscope is clear before the instrument is inserted into the endoscope. Do not use the instrument if you cannot see the distal part of the instrument inserted in the endoscope. Unclear vision when the instrument is inserted into the endoscope may result in injury to the patient, such as perforation, hemorrhage or mucosal damage, as well as damage to the endoscope and/or instrument.</p> <p>4) This device is intended for adult.</p> <p>5) Patients should be informed of the potential risks and complications, which may lead to injury or illness of the patient.</p> <p>6) The operation should be performed under good surveillance and necessary rescue equipment should be prepared in advance to ensure the safety and success of the operation.</p>
<b>Recommendations</b>	<p>PRODUCT DISPOSAL</p> <p>After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.</p>

**Device Description:**

PHOTOS, DRAWINGS	PHOTOS, DRAWINGS																																				
<p style="text-align: center;"><b>Assembly drawing for the proposed device</b></p>  <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 10%;">No.</th> <th style="width: 40%;">Part Name</th> <th style="width: 10%;">N o.</th> <th style="width: 40%;">Part Name</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Basket assembly</td> <td>9</td> <td>Position cap</td> </tr> <tr> <td>2</td> <td>Steel wire</td> <td>10</td> <td>Protection tube</td> </tr> <tr> <td>3</td> <td>Hypo tube</td> <td>11</td> <td>Boosting Tube</td> </tr> <tr> <td>4</td> <td>Heat shrink tube</td> <td>12</td> <td>Tension Tube</td> </tr> <tr> <td>5</td> <td>Dock tube2</td> <td>13</td> <td>Slide block</td> </tr> <tr> <td>6</td> <td>Coated spring tube</td> <td>14</td> <td>Tension block</td> </tr> <tr> <td>7</td> <td>Long tension Tube</td> <td>15</td> <td>Core rod</td> </tr> <tr> <td>8</td> <td>Tension tube</td> <td>/</td> <td>/</td> </tr> </tbody> </table>	No.	Part Name	N o.	Part Name	1	Basket assembly	9	Position cap	2	Steel wire	10	Protection tube	3	Hypo tube	11	Boosting Tube	4	Heat shrink tube	12	Tension Tube	5	Dock tube2	13	Slide block	6	Coated spring tube	14	Tension block	7	Long tension Tube	15	Core rod	8	Tension tube	/	/	<p style="text-align: center;"><b>Device illustration –proposed devices in package</b></p>  <p style="text-align: center;"><b>Device illustration –proposed devices without package</b></p> 
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8	Tension tube	/	/																																		

**Invasive device / non invasive device:** Invasive device

**Components:** materials of components

1.Product

Materials for the product are shown in as follows :

No.	Component	Material	
1	Basket assembly	Front cap	Stainless steel
		Front tube	Stainless steel
		Basket wire	Nitinol



## PRODUCT TECHNICAL FORM

No.	Component	Material
	Pipe	Stainless steel
	Connect tube	Stainless steel
2	Steel wire	Stainless steel
		Silicone oil
		Poly tetra fluoroethylene
3	Hypo tube	Stainless steel
4	Heat shrink tube	Poly tetra fluoroethylene
5	Dock tube2	Stainless steel
6	Coated spring tube	Stainless steel
		Poly tetra fluoroethylene
7	Long tension Tube	Stainless steel
8	Tension tube	Stainless steel
9	Position cap	Acrylonitrile Butadiene Styrene
10	Protection tube	Thermoplastic Elastomer
11	Boosting Tube	Stainless steel
12	Tension Tube	Stainless steel
13	Slide block	Acrylonitrile Butadiene Styrene
		Thermoplastic Elastomer
14	Tension block	Acrylonitrile Butadiene Styrene
15	Core rod	Acrylonitrile Butadiene Styrene

### 2. Packaging

A. Flexible peel pouch: Coated Tyvek 1073B+35791-E

B. Case box: single-wall corrugated fiberboard



## PRODUCT TECHNICAL FORM

C. Carton: double-wall corrugated fiberboard

Presence of:	YES	NO		YES	NO
Active substances		✓	Phtalate and DEHP		✓
PVC		✓	Bisphenol A		✓
Product of animal or biological origin		✓	Latex		✓

### Manufacturer

Manufacturer name	Micro-Tech (Nanjing) Co., Ltd.
Manufacturing location(s)	No.10 Gaoke Third Road, Nanjing National Hi- Tech, Industrial Development Zone Nanjing 210032, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA
Manufacturer Quality Assurance System	EN ISO 13485: 2016+A11 :2021

### Sterilisation

Sterilisation method	EO
Sterilisation location(s)	No. 199 Medicine Valley Avenue, Nanjing National Hi-Tech Industrial Development Zone, Nanjing 210032, Jiangsu Province, PRC.
Sterilisation control(s)	BI testing, EO Residue Test
Shelf Life	3 years

Storage conditions	This device should be stored in a clean, well-ventilated, non-corrosive gas environment with a service life of 3 years.
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CE Mark Number	CE0344
Notified body	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
European representative (full name, address and unique identification n°)	Shanghai International Holding Corp.GmbH(Europe) Eiffestrasse 80,20537 Hamburg Germany
Class of the device (I,IIa,IIb,III)	Class IIa
EMDN Code	G0305010202
GMDN Code	46452

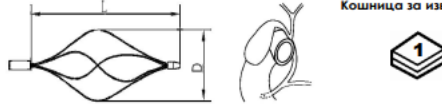


Labeling:  
Label on the Pouch



### Extraction Basket

Extraktionskorb Vierasesinekori Ekstraktionskurv Ekstrakčni košik Καλάθι εξαγωγής Panier d'extraction Cestello di estrazione	Extraktionskorg Extrakčný košik Ekstraksjonskurv Ekstrakcijas grozs Cesto de extracción Cesto de extracción Ekstrakcijska košara	Coş de extracție Extracție mand Eihvõlvik kosar Ekstrahermiskorvi Ištraukimo krepšelis Kosza do ekstrakcji Ekstrakciyon Sepeti Koşare za ekstrakciju КoшHицa зa изBлaчeHиe
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<b>Basket Diameter</b> 10 mm	<b>Channel Diameter</b> ≥1.1 mm
<b>Working Length</b> 2900 mm	<b>Basket Length</b> 30 mm

REF	CEB00000	2024-08-01
LOT	ME111111111	2027-07-31



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Extraction Basket REF CEB00000 LOT ME111111111  (01)06902284569515(17)270731(10)ME111111111	Extraction Basket REF CEB00000 LOT ME111111111  (01)06902284569515(17)270731(10)ME111111111
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DE REP Shanghai International Holding Corp. GmbH (Europe) Elferstrasse 60, 20537 Hamburg, Germany	CH REP MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland EU0CEB0000	UK Responsible Person Lotus Global Co., Ltd. 23 Mainie Street, Reading, RG2 6AG, England, United Kingdom P-100001267 REV 3 08/24
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Label on the case box

### Extraction Basket

Extrakční košík  
Extraktionskorb  
Vierasesinekori  
Ekstraktionskurv  
Καλάθι εξαγωγής  
Panier d'extraction  
Cestello di estrazione

Extraktionskorg  
Extrakčný košík  
Ekstraksjonskurv  
Ekstrakcijas grozs  
Cesto de extracção  
Cesta de extracción  
Ekstrakcijska košara

Cos de extractie  
Extractiemand  
Eltávolító kosár  
Ekstraheerimiskorvi  
Ištraukimo krepšelis  
Kosza do ekstrakcji  
Ekstraksiyon Sepeti  
Košare za ekstrakciju  
Кошница за извличане

Basket Diameter 10 mm

Channel Diameter ≥1.1 mm

Working Length 2900 mm

Basket Length 30 mm

<b>REF</b>	CEB00000		2024-08-01
<b>LOT</b>	ME111111111		2027-07-31

**UDI**

(01)16902284569512(17)270731(10)ME111111111

MD

STERILE/EO

CE  
0344

eifu.micro-tech.com.cn CAUTION. DESTROY IT AFTER USING

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### Extraction Basket

Basket Diameter 10 mm Channel Diameter ≥1.1 mm

Working Length 2900 mm Basket Length 30 mm

**REF** CEB00000 2024-08-12

**LOT** ME111111111 2027-08-11



Label on the Carton

## Extraction Basket

Extrakční košík  
Extraktionskorb  
Vierasesinekori  
Ekstraktionskurv  
Καλάθι εξαγωγής  
Panier d'extraction  
Cestello di estrazione

Extraktionskorg  
Extrakčný košík  
Ekstraksjonskurv  
Ekstraksijas grozs  
Cesto de extração  
Cesta de extracción  
Ekstrakcijska košara

Coș de extracție  
Extractiemand  
Eltávolító kosár  
Ekstraheerimiskorvi  
Ištraukimo krepšelis  
Kosza do ekstrakcji  
Ekstraksiyon Sepeti  
Košare za ekstrakciju  
Кошница за извличане

Basket Diameter 10 mm

Channel Diameter ≥1.1 mm

Working Length 2900 mm

Basket Length 30 mm

<b>REF</b>	CEB0000		2024-08-01
<b>LOT</b>	ME111111111		2027-07-31

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CAUTION, DESTROY IT AFTER USING

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**EUOCEB0000**

P-100001268 REV 3 08/24









## PRODUCT TECHNICAL FORM

Simple or double	1 piece simple
Number of units per sterile packaging unit	1pc/pouch, 10 pouch/ case box, 10 case boxes/ carton
Final packaging	Carton
Product conservation	Packed as the packaging.



## PRODUCT TECHNICAL FORM

Revision	Date	Description
A/0	2024-08-12	Initial