

# StoneBuster®

"Injectable" Mechanical Lithotripsy System

## "Injectable" Mechanical Lithotripsy System

- Unique StoneBuster® Handle  
*User-friendly Twist & Pull Technology Delivers High Basket Tension to Biliary Stones*
- Effective One Step Stone Crushing Version  
*Papilla Cannulation, Biliary Stone Capture & Crushing without Exchange of Components*
- Highly sophisticated System Concept  
*Safe & Reliable Management of Emergency Lithotripsy Cases*  
*Pre-assembled Set Configurations for Specific Treatment Requirements*  
*Convenient Handling for the Assembly & Detachability of Components*



 **Medi-Globe®**  
*The Spirit of Care.™*



### StoneBuster® – "Injectable" Mechanical Lithotripsy System

The StoneBuster® system is a very comprehensive and effective system intended to crush and to manage large and impacted stones in the common bile duct via flexible endoscopy.

The unique StoneBuster® Handle is user friendly and is capable of providing sufficiently high tensions to the surface of a biliary stone via the metal spiral and lithotripsy basket components of the system, resulting in crushing of the stone. One of the key advantages, apart from the power and user-friendliness of the StoneBuster® system is the ability to effectively and safely manage an emergency lithotripsy case without significantly increasing risk to the patient.

In addition to the overall flexibility of the StoneBuster® system, it also offers the convenience of easy assembly and fewer device components. Medi-Globe offers individual or set system components and is available in single use or reusable formats.

The StoneBuster® system offers a wide range of treatment options. The pre-assembled, sterile and ready to use Stone Crushing Set, (GML-11-26-XXX) in combination with the StoneBuster® Handle, (GML-99-01-000) offer the possibility to

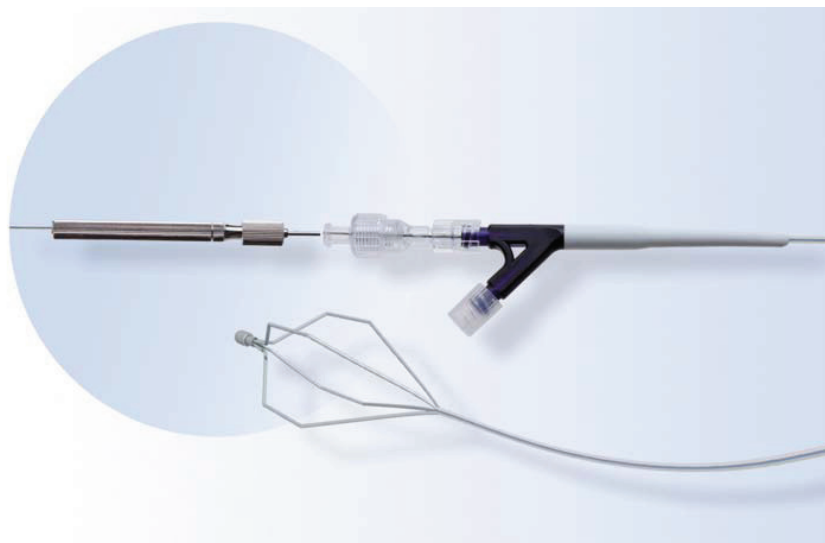
- cannulate the papilla,
- capture a biliary stone and
- crush it, all without exchange of system components.

The metal spiral is equipped with a Luer-lock port making it possible to inject contrast as necessary during the procedure.

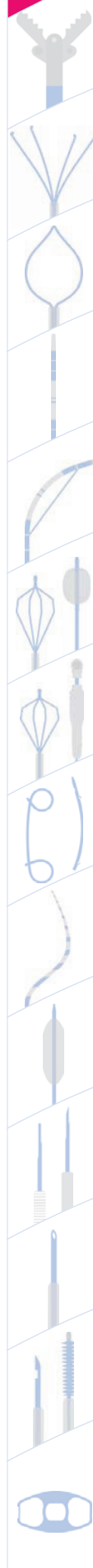
#### One Step Stone Crushing Set



#### Basket Insertion Set



For patients with difficult anatomies, cannulation of the biliary system is made easier with the StoneBuster's pre-assembled Basket Insertion Set, (GML-06-26-XXX). After easier cannulation and positioning of the basket is performed by using the softer and more flexible Basket Insertion Set, the plastic sheath of the Basket Insertion Set is replaced by an "injectable" metal spiral (GML-91-26-180). The process of mechanical lithotripsy is then completed by attachment and utilization of the StoneBuster® Handle, (GML-99-01-000) to crush the biliary stone(s).



### Basket Insertion Set Pre-assembled

Single Use Lithotripsy Basket (Length 400 cm) housed in an “Injectable” Plastic Sheath with Sealing Cap (Length 180 cm) and connected with an Instrument Holder, sterile packed

Catalog No.	Description	Sheath Outer Diameter	Basket Diameter	Minimum Accessory Channel Diameter
GML-06-26-420	4-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-06-26-425	4-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-06-26-430	4-Wire Basket	2.6 mm	30 mm	2.8 mm
GML-06-26-620	6-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-06-26-625	6-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-06-26-630	6-Wire Basket	2.6 mm	30 mm	2.8 mm

### “Injectable” Basket

Single Use Lithotripsy Basket (Length 280 cm), sterile packed

Catalog No.	Description	Basket Diameter
GML-02-26-420	4-Wire Basket	20 mm
GML-02-26-425	4-Wire Basket	25 mm
GML-02-26-430	4-Wire Basket	30 mm
GML-02-26-620	6-Wire Basket	20 mm
GML-02-26-625	6-Wire Basket	25 mm
GML-02-26-630	6-Wire Basket	30 mm

### “Injectable” Basket

Reusable Lithotripsy Basket (Length 280 cm)

Catalog No.	Description	Basket Diameter
GML-52-26-420	4-Wire Basket	20 mm
GML-52-26-425	4-Wire Basket	25 mm
GML-52-26-430	4-Wire Basket	30 mm
GML-52-26-620	6-Wire Basket	20 mm
GML-52-26-625	6-Wire Basket	25 mm
GML-52-26-630	6-Wire Basket	30 mm

### Individual & Replacement Components

For “Injectable” Mechanical Lithotripsy System

Catalog No.	Description	Outer Diameter	Minimum Accessory Channel Diameter
GML-99-01-000	StoneBuster® Handle, reusable		
GML-91-26-180	“Injectable” Metal Spiral (Length 180 cm), reusable, sterile packed	2.6 mm	2.8 mm
GML-90-34-080	Emergency Spiral (Length 80 cm), reusable, sterile packed	3.4 mm	Not applicable
100601	Instrument Holder, reusable		

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Medi-Globe GmbH  
Medi-Globe Straße 1-5  
83101 Achenmühle  
Germany**

for the scope

**products class is:** biopsy forceps, foreign body retrievers, E.R.C.P. catheters, stone extractions baskets, mechanical lithotriptors and baskets, guide wires, cytology brushes, pushers, nasal tubes, spray catheters, guiding catheters, dilation balloons

has introduced and applies a

## Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

## Annex V – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2019-06-18
Valid until	2022-06-22
Registration no.	D1314600025
Report no.	P17-00553-95674
Stuttgart	2019-06-18

  
Head of Certification Body



# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Medi-Globe GmbH  
Medi-Globe Straße 1-5  
83101 Achenmühle  
Germany**

for the scope

**Endoscopic instruments, Drainage systems,  
HF - instruments and accessories, Needle systems  
(see attachment)**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex II – excluding Section 4  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-06-14
Valid until	2022-06-22
Registration no.	D1314600024
Report no.	P17-00553-95676
Stuttgart	2019-06-14



Head of Certification Body



**Attachment of the certificate**

**No. D1314600024**

Date 2019-06-14

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Product category	Product	Class
Drainage systems	Self-expanding metal stents (biliary, esophageal, intestinal)	IIb
	Pancreatic stents / sets	IIb
	Biliary stents / sets	IIb
	Nasal biliary drainages / sets	IIa
Endoscopic instruments	Multi-band ligator	IIa
	Extraction bags	IIa
	Hemostasis-Clip-System	IIa
	Biopsy valve with irrigation channel, non sterile	IIa
HF - instruments and accessories	HOT Biopsy Forceps	IIb
	High frequency handle for polypectomy snares and sphincterotomes	IIb
	Polypectomy snares	IIb
	Sphincterotomes	IIb
Needle systems	Aspiration needles for bronchoscopy and gastroscopy	IIa
	Aspiration needle systems for ultrasound endoscopy	IIa
	Fibrin needles	IIa
	Injection needles	IIa



Head of Certification Body