

StoneBuster®

"Injectable" Mechanical Lithotripsy System

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- 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



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

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

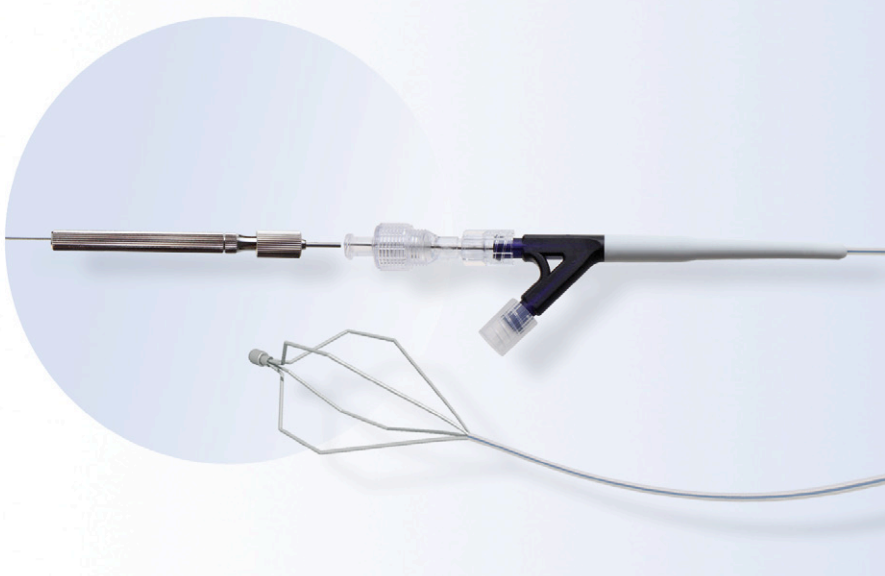
The metal spiral is equipped with a Luer-lock port making it possible to inject contrast as necessary during the procedure.

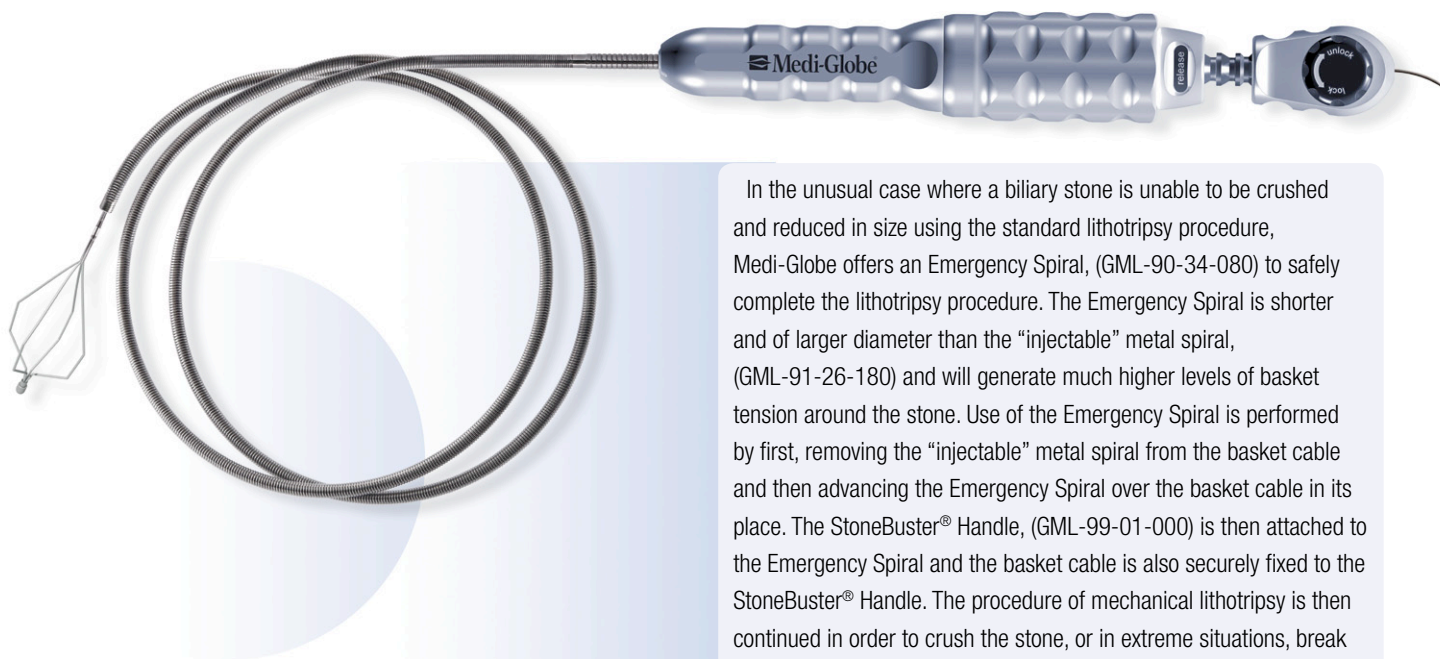
One Step Stone Crushing Set



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).





Safe and Reliable Management of
Emergency Lithotripsy Cases

In the unusual case where a biliary stone is unable to be crushed and reduced in size using the standard lithotripsy procedure, Medi-Globe offers an Emergency Spiral, (GML-90-34-080) to safely complete the lithotripsy procedure. The Emergency Spiral is shorter and of larger diameter than the “injectable” metal spiral, (GML-91-26-180) and will generate much higher levels of basket tension around the stone. Use of the Emergency Spiral is performed by first, removing the “injectable” metal spiral from the basket cable and then advancing the Emergency Spiral over the basket cable in its place. The StoneBuster® Handle, (GML-99-01-000) is then attached to the Emergency Spiral and the basket cable is also securely fixed to the StoneBuster® Handle. The procedure of mechanical lithotripsy is then continued in order to crush the stone, or in extreme situations, break the basket wire(s) allowing the stone to be released and the basket safely removed from the patient.

StoneBuster® – “Injectable” Mechanical Lithotripsy System

StoneBuster® “Silver Case Edition” Starter Set

Catalog No.	Description
GML-99-02-000S	<p>“Injectable” Mechanical Lithotripsy System composed in a stylish “Silver Case” including</p> <ul style="list-style-type: none"> → 1 x StoneBuster® Handle (GML-99-01-000), reusable → 2 x “Injectable” Metal Spirals (GML-91-26-180), reusable → 1 x Emergency Spiral (GML-90-34-080), reusable → 1 x Instrument Holder (100601), reusable → 1 x 4-Wire Basket with 25 mm basket diameter (GML-02-26-425), single use → 1 x 4-Wire Basket with 30 mm basket diameter (GML-02-26-430), single use → 1 x 6-Wire Basket with 30 mm basket diameter (GML-02-26-630), single use

Stone Crushing Set Pre-assembled

Single Use Lithotripsy Basket (Length 280 cm) housed in an “Injectable” Metal Spiral (Length 180 cm) and connected with an Instrument Holder, sterile packed

Catalog No.	Description	Sheath Outer Diameter	Basket Diameter	Minimum Accessory Channel Diameter
GML-11-26-420	4-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-11-26-425	4-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-11-26-430	4-Wire Basket	2.6 mm	30 mm	2.8 mm
GML-11-26-620	6-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-11-26-625	6-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-11-26-630	6-Wire Basket	2.6 mm	30 mm	2.8 mm

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		

StoneBuster® – Standard Mechanical Lithotripsy System

The following sets and components are for Standard (Non-Injectable) Mechanical Lithotripsy Systems, which are available and in use in several markets.

Basket Insertion Set Pre-assembled

Single Use Lithotripsy Basket (Length 400 cm) housed in a Plastic Insertion Sheath with Injection Port and 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-01-26-420	4-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-01-26-425	4-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-01-26-430	4-Wire Basket	2.6 mm	30 mm	2.8 mm
GML-01-26-620	6-Wire Basket	2.6 mm	20 mm	2.8 mm
GML-01-26-625	6-Wire Basket	2.6 mm	25 mm	2.8 mm
GML-01-26-630	6-Wire Basket	2.6 mm	30 mm	2.8 mm

Basket Insertion Set

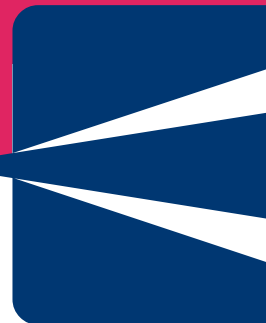
Reusable Lithotripsy Basket (Length 400 cm), Reusable Plastic Insertion Sheath with Injection Port (Length 180 cm), Reusable Instrument Holder and Single Use Sealing Cap

Catalog No.	Description	Sheath Outer Diameter	Basket Diameter	Minimum Accessory Channel Diameter
601420S	4-Wire Basket	2.6 mm	20 mm	2.8 mm
601425S	4-Wire Basket	2.6 mm	25 mm	2.8 mm
601430S	4-Wire Basket	2.6 mm	30 mm	2.8 mm
603420S	6-Wire Basket	2.6 mm	20 mm	2.8 mm
603425S	6-Wire Basket	2.6 mm	25 mm	2.8 mm
603430S	6-Wire Basket	2.6 mm	30 mm	2.8 mm

Individual & Replacement Components

Standard Mechanical Lithotripsy System

Catalog No.	Description	Outer Diameter	Minimum Accessory Channel Diameter
GML-99-01-000	StoneBuster® Handle, reusable		
GML-90-26-180	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
600302	Plastic Insertion Sheath with Injection Port (Length 180 cm), reusable	2.6 mm	2.8 mm
600303	Instrument Holder, reusable		
601001	Sealing Cap, Single use, sterile packed		



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