Endoscopic Ultrasound-Guided FNA System - Single Use



- Twist-Lock Technology for Sheath & Needle Length Adjustment One hand operation
 - Needle length adjustment (0 8.5 cm)
- Enhanced Clear Indicators Provide a safe & intuitive lock and unlock handling of the adjustment rings
- Specially Treated Needle Superior needle visibility
- Versions with Unique Sheath Stabilizer Controlled needle advancement in large channel scopes
- Optimized Lighter Stylet for a Comfortable Stylet Management Easier coiling of the stylet for storage
 - Faster stylet insertion time
- Colored Plastic Sheath More precise needle placement and better performance in angulated endoscope positions

She Spirit of Care.

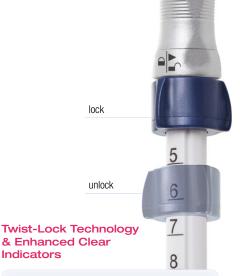
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The patented Twist-Lock Technology is an user-friendly and screwless locking and unlocking mechanism. It allows the user to control all adjustments easily by turning a ring with one-hand operation.

Enhanced clear indicators show the lock / unlock direction and the setting of the system to assure a safe and intuitive handling.

The needle length ranges from 0 - 8.5 cm.



The new stylet design is decreased in weight compared to the previous version and features less swing and float movements. The well-engineered design results in:

- Easier coiling of the stylet for storage
- Faster stylet insertion time

beveled

round



Unique Sheath Stabilizer

Selected needle versions are featured with a Sheath Stabilizer. The Sheath Stabilizer is a 10 cm long plastic tube at the distal catheter tip enlarging the catheter diameter from 1.8 mm to 2.7 mm. The Stabilizer significantly facilitates a controlled needle advancement through large channels endoscopes (3.2 mm, 3.7 mm, 3.8 mm) and maintains a firm needle position onto the targeted lesion.

All versions are equipped with a flexible blue-colored plastic catheter for a precise needle performance also in angulated endoscope positions.

Super Beveled Needle & Stylet Designs

The SonoTip Pro Control systems feature a 15° beveled and sharp needle design for an easy and atraumatic puncture in hard lesions. This sharp needle cut results in a large needle lumen exposure for enhanced acquisition of cyto-histopathological specimen.

Round and beveled stylets are offered to meet user's technique preferences to puncture.

25 Gauge

SonoTip [®] Pro Control – with round stylet			
Catalog No.	Description	Needle Diameter	Catheter Outer Diameter
GUS-33-18-025	EUS-Guided FNA System with Twist-Lock Technology	25 Gauge 0.5 mm	1.8 mm
GUS-33-27-025	EUS-Guided FNA System with Twist-Lock Technology → Tip Stabilizer to accommodate large working channels (e.g. 3.2 mm, 3.7 mm, 3.8 mm)	25 Gauge 0.5 mm	2.7 mm

22 Gauge

SonoTip[®] Pro Control – with round stylet

Catalog No.	Description	Needle Diameter	Catheter Outer Diameter
GUS-33-18-022	EUS-Guided FNA System with Twist-Lock Technology	22 Gauge 0.7 mm	1.8 mm
GUS-33-27-022	EUS-Guided FNA System with Twist-Lock Technology → Tip Stabilizer to accommodate large working channels (e.g. 3.2 mm, 3.7 mm, 3.8 mm)	22 Gauge 0.7 mm	2.7 mm

SonoTip® Pro Control - with beveled stylet

Catalog No.	Description	Needle Diameter Catheter Outer Diameter
GUS-34-18-022	EUS-Guided FNA System with Twist-Lock Technology	22 Gauge 1.8 mm 0.7 mm
GUS-34-27-022	 EUS-Guided FNA System with Twist-Lock Technology → Tip Stabilizer to accommodate large working channels (e.g. 3.2 mm, 3.7 mm, 3.8 mm) 	22 Gauge 2.7 mm 0.7 mm

19 Gauge

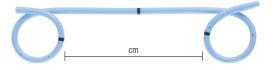
SonoTip [®] Pro Control – with round stylet			
Catalog No.	Description	Needle Diameter	Catheter Outer Diameter
GUS-33-21-019	EUS-Guided FNA System with Twist-Lock Technology → Compatible with guide wires of maximal Ø .030" (Recommended Medi-Globe catalog no. GGW-08-30-400)	19 Gauge 1.1 mm	2.1 mm

The 19 Gauge SonoTip Pro Control is perfect for EUS wire guided access management in the biliary-pancreatic system. The 19 Gauge needle is compatible to guide wires with a maximum diameter of .030".

Especially for cyst-drainages Medi-Globe's cyst guide wire GGW-08-30-400 is recommended. This guide wire comprises of an uncoated Nitinol wire with a 15 cm flexible radiopaque spring. The non-coating feature prevents shearing of Teflon coating during needle / guide wire manipulating.

Components for SonoTip® Pro Control EUS-FNA Line

Cyst Guide Wire – compatible with 19-Gauge EUS-FNA systems for cyst drainage			
Catalog No.	Description	Diameter	Length
GGW-08-30-400	Uncoated Nitinol wire with a 15 cm flexible radiopaque spring	.030" (0.75 mm)	400 cm



Pseudo-Cyst Double Pigtail Stent Sets - with position markers

Catalog No.	Stent		Pusher	
	Size / French			
GBS-11-08-002S	8.5	2 cm	8.5	220 cm
GBS-11-08-005S	8.5	5 cm	8.5	220 cm
GBS-11-08-007S	8.5	7 cm	8.5	220 cm
GBS-11-08-009S	8.5	9 cm	8.5	220 cm
GBS-11-10-002S	10.0	2 cm	10.0	220 cm
GBS-11-10-005S	10.0	5 cm	10.0	220 cm
GBS-11-10-007S	10.0	7 cm	10.0	220 cm
GBS-11-10-009S	10.0	9 cm	10.0	220 cm

The pseudo-cyst double pigtail stent is also available as single component. (Catalogue no without "S").



Aspiration Syringe with filling volume of 20 ml	
Catalog No.	Description
VAC120	VacLok Syringe 20 ml

Medi-Globe - a trendsetter in EUS needle systems from the beginning

One major milestone was the development of a flexible ultrasound endoscope with a convex transducer and a working channel in the early 1990s by Pentax. At the same time, Prof. Dr. Vilmann and his team at the Gentofte University Hospital in Copenhagen, Denmark performed studies into different EUS needle prototypes for this endoscope.

In 1994 Medi-Globe GmbH pioneered the most promising protoype into a reliable medical product. The first commercially available EUS-FNA system, known as Hanke-Vilmann needle, was launched and for many years the EUS needle of choice.

This Hanke-Vilmann system consisted of a long steel needle with a stylet, a reusable metal spiral and a reusable aluminum handle for moving the needle.

In 2002, Medi-Globe GmbH introduced the first complete sterile system for single-use with its SonoTip II model. In contrast to the Hanke-Vilmann needle, this is directly compatible with all standard EUS endoscopes from leading manufacturers thanks to its specialized adjustment system. The product portfolio has been permanently expanded with the addition of new needle materials, innovative needle coatings and improved technologies for visibility of the needle under ultrasound.

In 2011, Medi-Globe introduced the next generation of its EUS-FNA under the brand name SonoTip Pro Control. This has a much more ergonomic handle. The most significant innovation was however its patented and completely new Twist-Lock technology, for adjusting sheath length and needle depth. Settings can now be adjusted very comfortably with one hand by the physician. The new model also integrates a plastic sheath, which is more flexible than the spirals of SonoTip II models, and which allows excellent needle insertion even at extremely sharp endoscope position angles.

In 2015, Medi-Globe significantly improved the SonoTip Pro Control's usability. Enhanced clear indicators show the lock and unlock direction to assure a safe and intuitive handling pertaining the Twist-Lock Technology for sheath & needle length adjustment.

Additionally, an optimized stylet provides an excellent and comfortable stylet management.

EBUS-TBNA

Ultrasound endoscopy is in the meantime no longer merely restricted to gastrointestinal tract diagnoses, but has also found further use with endobronchial ultrasound guided transbronchial needle aspiration (EBUS-TBNA) in bronchoscopy.

Medi-Globe also offers a powerful solution in this specialized area, with its SonoTip EBUS Pro Flex. For this application, Medi-Globe became the first manufacturer of a needle completely made from Nitinol. This is dimensionally stable and prevents any mechanical needle deformation, which can occur with other needle materials when the needle is fed into an angled endoscope.

Please contact Medi-Globe GmbH for special information pertaining to EBUS-TBNA systems or visit our website: <u>www.medi-globe.de</u>.



SonoTip® Pro Control

Endoscopic Ultrasound-Guided FNA System - Single Use



www.medi-globe.de

Manufactured by: