

Drain-TG™

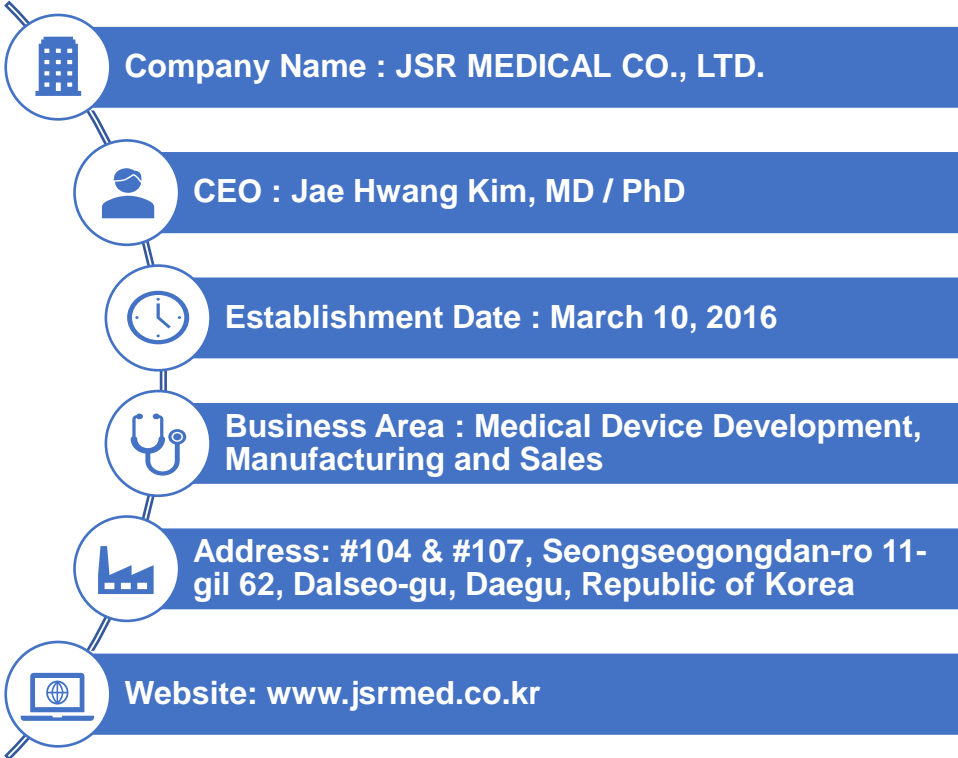
- English Instruction Manual -



JSR MEDICAL



❖ Company Information



❖ Vision

“JSR Medical holds the cutting-edge minimally invasive colorectal surgical technology.

We develop innovative surgical device and treatment method which minimize patient’s stress and promote fast recovery.

Our goal is to enhance patient’s quality of life through development of revolutionary surgical device and technology.”





❖ Company History

- Mar 2016 Establishment of JSR Medical Co., Ltd.
- Apr 2016 Medical Device Sales Registration (MFDS 2016-3430019-00008)
- Aug 2018 DGIST Authentication (Industry-University Cooperation 2018-031)
- Nov 2018 Frontier Venture Certification (0068)
- May 2020 Medical Device Manufacturer Registration (MFDS 6855)
- Jul 2020 Medical Device Manufacturing & Exportation Certification (MFDS 20-550)
- Nov 2020 Excellent Technology Company Certification (FTS-2020-03072)
- Nov 2020 Venture Company Certification (20200116111)
- Dec 2020 Manufacturing Facility Registration (272902020549805)
- Jan 2021 ISO 13485:2016 Approval (GIS-5073-MD)
- Nov 2021 Corporate R&D Center Registration (2021115800)
- Jan 2022 KGMP Approval (KCL-AABA-13323)
- Jul 2022 EN ISO 13485:2016 Approval (Medical Device Class IIa & Class III)
- Aug 2022 FDA Device Registration (Medical Device Class I)
- Dec 2022 MDSAP Approval (MDSAP 757220)
- Jan 2023 FDA IDE Approval (G220334 – Medical Device Class III)
- Apr 2023 U.S. Pivotal Clinical Trial Start (Multi-center)



Drain-TG Models & Specification

1. Model No.: DTG02-18

Disposable surgical guide (30cm) for round-type drainage tubes to be inserted to the desired area during surgery. For drain size 18Fr (6mm) or less.



2. Model No.: DTG02-JP

Disposable surgical guide (30cm) for Jackson-Pratt drainage tube. For drain size 7-10mm in width.



3. Model No.: DTG02-J2

Disposable surgical guide (long version: 45cm) for Jackson-Pratt drainage tube. For drain size 7-10mm in width.





Drain-TG can be applied in any general surgery that requires drain tube insertion.

Product Description

Product Name	Disposable Drain-TG™
Model No.	DTG02-18
Intended Use	Surgical guide for drainage tube to be inserted to the desired area during surgery
FDA Device Listing No.	D480270
Raw Material	STS304, Medical Polycarbonate
Sterilization	EO sterilized
Etc.	Disposable device (Do not re-use)

Product Specification



Model No.	Length	Width	Height
DTG02-18	300mm	90mm	28mm

Product Composition

Distal End

1. Blunt tip design minimizes peritoneal damage when inserted
2. About 35° angle design for the distal end to prevent clogging of the pipe when inserting
3. Composed of medical-grade polycarbonate that are safe for the human body
4. Excellent tensile strength between Distal End and Pipe (Cpk > 1.67)

Pipe

1. Composed of STS304 that are safe for the human body
2. 0.4t for Lightweight
3. Excellent bending strength (Cpk > 1.67)

Handle

1. Optimized grip with ergonomic design
2. Notch design for easier inserting direction change
3. Composed of medical-grade polycarbonate that are safe for the human body

Specification

Compatible for round drain tubes of size 18Fr or less

※ Note: If the drain tube is cross-type with an external diameter of 18Fr., it may not fit due to the deviation of the joint external diameter by different manufacturers. Please check whether the drain tube fits the device before use.



Drain-TG can be applied in any general surgery that requires drain tube insertion.

Product Description

Product Name	Disposable Drain-TG™
Model No.	DTG02-JP
Intended Use	Surgical guide for drainage tube to be inserted to the desired area during surgery
FDA Device Listing No.	D480270
Raw Material	STS304, Medical Polycarbonate
Sterilization	EO sterilized
Etc.	Disposable device (Do not re-use)

Product Specification



Model No.	Length	Width	Height
DTG02-JP	300mm	90mm	28mm

Product Composition

Distal End

1. Blunt tip design minimizes peritoneal damage when inserted
2. About 35° angle design for the distal end to prevent clogging of the pipe when inserting
3. Composed of medical-grade polycarbonate that are safe for the human body

Pipe

1. Composed of STS304 that are safe for the human body
2. 0.3t for Lightweight
3. Excellent bending strength (Cpk > 1.67)

Handle

1. Optimized grip with ergonomic design
2. Notch design for easier inserting direction change
3. Composed of medical-grade polycarbonate that are safe for the human body

Specification

Compatible for flat drain tubes of width size 7-10mm

※ Note: the drain tube may not fit due to the deviation of the joint external width or height by different manufacturers. Please check whether the drain tube fits the device before use.



Drain-TG can be applied in any general surgery that requires drain tube insertion.

Product Description

Product Name	Disposable Drain-TG™
Model No.	DTG02-J2
Intended Use	Surgical guide for drainage tube to be inserted to the desired area during surgery
FDA Device Listing No.	D480270
Raw Material	STS304, Medical Polycarbonate
Sterilization	EO sterilized
Etc.	Disposable device (Do not re-use)

Product Specification



Model No.	Length	Width	Height
DTG02-J2	450mm	90mm	28mm

Product Composition

Distal End

1. Blunt tip design minimizes peritoneal damage when inserted
2. About 35° angle design for the distal end to prevent clogging of the pipe when inserting
3. Composed of medical-grade polycarbonate that are safe for the human body

Pipe

1. Composed of STS304 that are safe for the human body
2. 0.3t for Lightweight
3. Excellent bending strength (Cpk > 1.67)

Handle

1. Optimized grip with ergonomic design
2. Notch design for easier inserting direction change
3. Composed of medical-grade polycarbonate that are safe for the human body

Specification

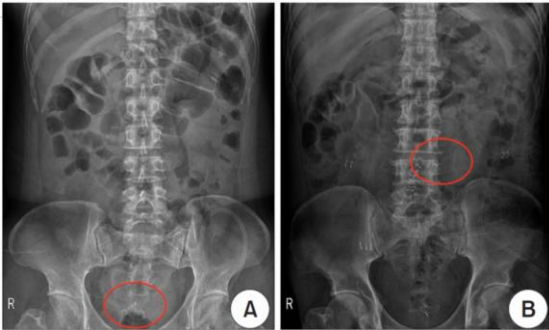
Compatible for flat drain tubes of width size 7-10mm

※ Note: the drain tube may not fit due to the deviation of the joint external width or height by different manufacturers. Please check whether the drain tube fits the device before use.



Drain-TG Characteristics

- New technology (preperitoneal fat plane tunneling device)
- Treatment can begin before the diagnosis
- Accurate reach + fixation to anastomosis site
- No migration for more than 2 - 3 weeks
- No surgical interventional necessary in most AL cases
- Short-term treatment possible (short-term NPO with antibiotics)

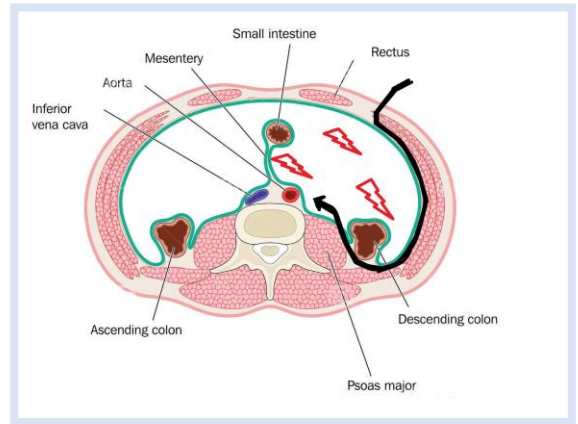


(A) Good position

(B) Drain Migration

EP Tunneling Method

- Preperitoneal fat plane tunneling
- Enter to intraabdominal cavity near the anastomotic site
- No migration for more than 2 - 3 weeks



Regulatory & Patent Registration Status

Certification				
Status	Approved	Approved	Approved	Approved
Patent	- KOREA: 3 Patent Registered (10-2022-0075924, 10-2022-0081857, 10-2022-0085505) - PCT: 3 Patent Registered (PCT/KR2022/016170, PCT/KR2022/016171, PCT/KR2022/016173)			