A young female patient after gynecological surgery, was diagnosed with **infertility**.

A patient who survived colon cancer, **died of bowel obstruction**.

A girl after pelvic surgery, suffered from **chronic pelvic pain**.

A man after laparoscopic surgery, had experienced **enterobrosia**.

A patient after nasal surgery, had **six more repeated surgeries**.

…because of **ADHESION**.

Innovation of Surgical adhesion barrier

MEDICURTAIN®

Up to 93% of patients develop adhesions after all kinds of surgeries, which result in the following clinical consequences: [1)]

- Bowel obstruction up to 74%
- Infertility up to 20%
- Chronic pelvic pain up to 50%
- Repeated surgery in 35% of patients within 10 years
- Intestinal perforation during following surgery up to 19% [2)]

Global anti-adhesion barrier market is expected to be US$ 2.7 billion by 2022. [3)] However…

What are the problems of currently marketed surgical adhesion barriers?

Film type	Gel/solution type
• Difficult to use (self-rolling) • Limited to use on laparoscopy & hysteroscopy	• Less efficacy because of low viscosity • Required to remove residual materials in solution type

The solution to the current problems

Innovation of Surgical adhesion barrier

MEDICURTAIN®

Core Advantages

✓ **Novel dual mechanism of action based on patented technology**
Supreme viscosity + anti-coagulation effect

✓ **CE certification & German FSC**
Verified leading edge technology of Shin Poong

✓ **Proven efficacy & safety**
By the largest clinical studies (> 680 patients)

✓ **Easier & faster**
Easy to use in operations, even for beginners

Ref. 1) Ann, R. Coll. Surg. Engl., 1993
2) Eur.J.Surg., Suppl, 1997
3) Global Industry Analysts, Inc., 2016

Innovation of Dual Anti-adhesion Tech

Hyaluronic acid (HA): Advanced physical barrier	Hydroxyethyl starch (HES): Anti-coagulation effect
Supreme viscosity based on the patented technology	Blood clotting inhibition to prevent from adhesion

Indications & Dosage

- **Anti-adhesions during surgery**
  Medicurtain® is intended to prevent or reduce the post-surgical adhesion formation after hysteroscopic, abdominal, spinal, thyroid and nasal/sinus surgeries.

- 1.2 mL, 2.0 mL and 5.0 mL
- Pre-filled syringe

5 Pivotal Clinical Trials

Indication	Hysteroscopic surgery	Laparoscopic surgery	Spinal surgery	Thyroid surgery	Nasal/sinus surgery	Total
Number of patients	223	107	87	186	77	680

What is Hydroxyethyl starch (HES)? [1)]

- A natural waxy starch derived from corn
- Widely used as biocompatible substitute material whose safety is well-established

Medical Characteristics of HES

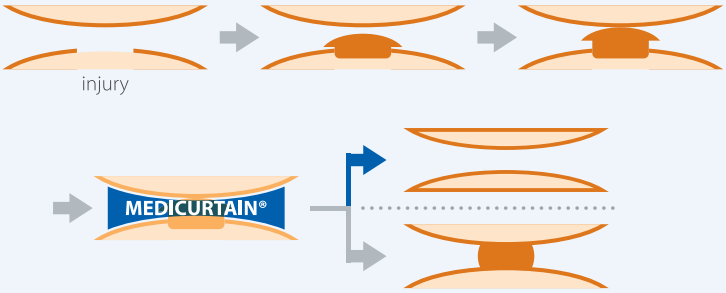
- Anti-inflammatory effect [2)]
- Anti-coagulation effect
- Biodegradable & biocompatible [3)]
- Safety [4)]

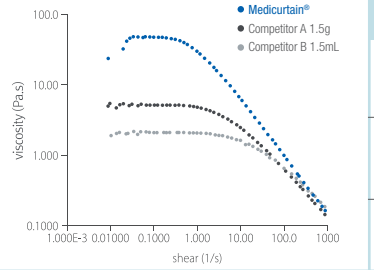
Ref. 1) Devy et al., 2005
2) Matharu et al., 2008
3) Park et al., 2010
4) Warren et al., 1996

Dual Mechanism of Action

HA : Advanced physical barrier effect of innovatively improved viscosity

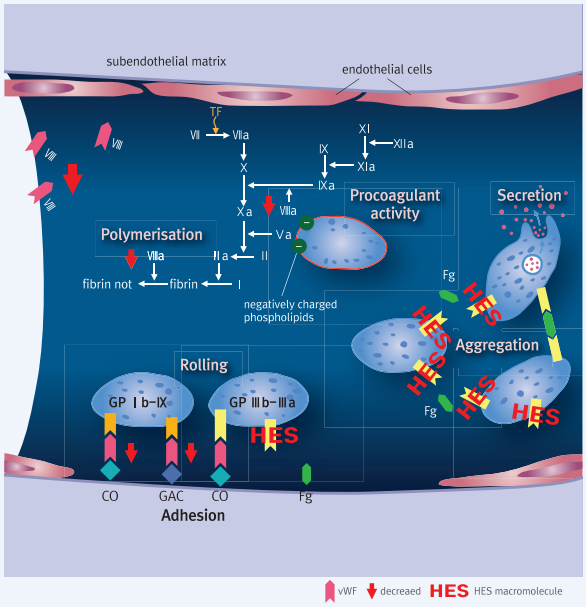
HES : Anti-coagulation effect





Product	Shear rate	Viscosity
Medicurtain®	0.1002 1/s	48.28 Pa.s
Competitor A	0.1002 1/s	5.29 Pa.s
Competitor B	0.1002 1/s	2.12 Pa.s

Shear Rate : Temporal change of shear. Indicated by a temporal change in the imaginary angle between two straight lines.



▲ HES(Anti-coagulation effect) [1]

Global Competitor Comparison Table

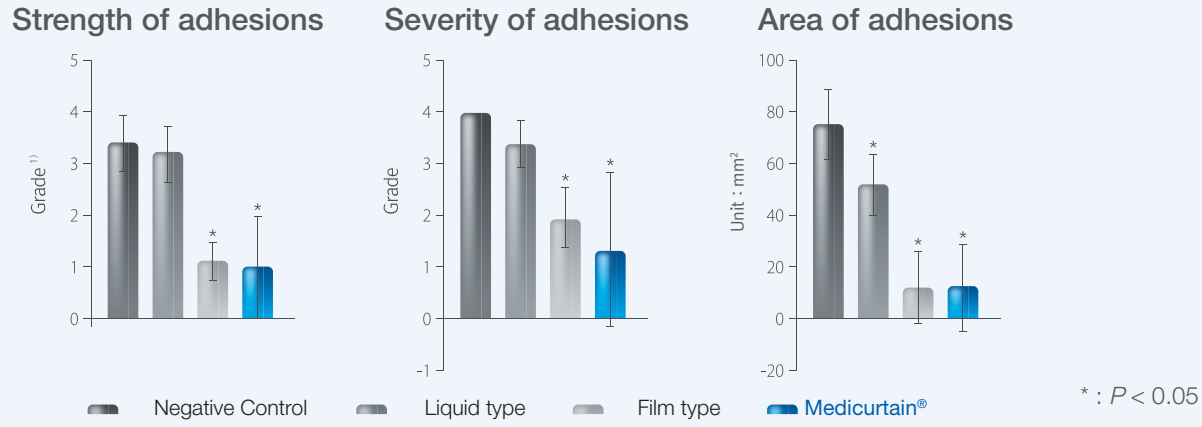
Comparison Item	Medicurtain®	S company S product	F company O product	C company S product	B company A product
Type	Gel	Film	Gel	Gel	Solution
Ingredient	Sodium hyaluronate + hydroxyethyl starch	Sodium hyaluronate + carboxymethyl cellulose	Polyethylene oxide + carboxymethyl cellulose	Polyethylene oxide + sodium hyaluronate	Icodextrin
Mechanism of Action	Dual (Physical barrier + anti-coagulation)	Physical barrier only	Physical barrier only	Physical barrier only	Hydrofloat
Global Patent	24 countries till 2029 (including USA, EU, China)	NA	NA	NA	NA
Viscosity on target tissues (*In vitro* lab grade test)	Grade 1 (Top)	Grade 1	Grade 3	NA	Grade 4 (Lowest)
Safety	Clinically proven safety (No contraindication in pregnancy)	Suspicion on 21 death	Pilot small study only	Severe pain reported	Clinically proven
Efficacy	Clinically proven efficacy	Limited to on endo-scopic surgeries	Pilot small study only	Pilot small study only	Similar to saline

Ref. 1) Sibylle et al., 2005

Pre-Clinical Study

Results

- Medicurtain® shows significantly superior efficacy compared to liquid type and normal saline.
- Medicurtain® shows equivalent efficacy to film-type.



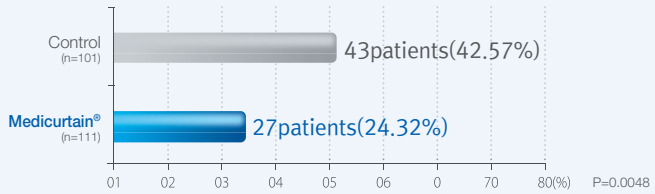
Method : Testing for the grade, strength and area of adhesion after grouping as Medicurtain®, film-type adhesion barrier, liquid-type adhesion barrier, and nomal saline.

Phase III Clinical Study : Hysteroscopic Surgery

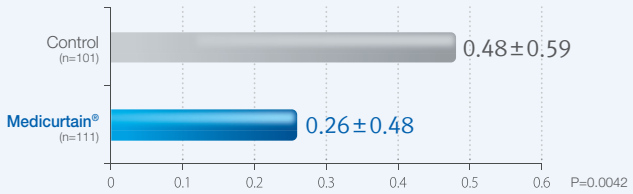
Results

Incidence and severity of adhesions were significantly reduced in the Medicurtain® group compared to the control group.

1) Incidence of adhesions (ITT)



2) Severity of adhesions (ITT)



Study Design : Multicenter, randomized, blind, placebo controlled study for evaluation efficacy and safety of the Medicurtain®. (N=223)

Method : Comparison in the adhesion formation rates & grades following the 4 weeks after hysteroscopic surgery.

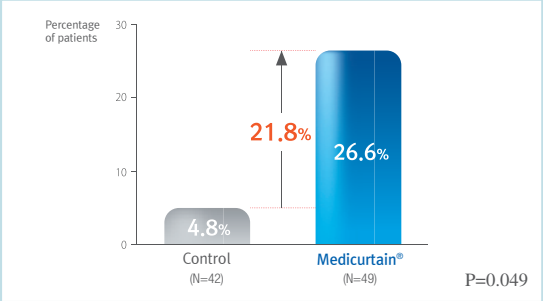
Ref. 1) Mazuji et al., 1964

Phase III Clinical Study : Laparoscopic Surgery

Results

Non-incidence of adhesion rate was significantly increased in the Medicurtain® group compared to the control group.
Medicurtain® group's **non**-incidence of adhesion rate was 21.8% higher than the control group.

1) **Non**-incidence of adhesions (ITT)



2) Severity of adhesions

Classification	Grade 0	Grade 1	Grade 2	Grade 3
Control	2(5%)	23(55%)	13(31%)	4(9%)
Medicurtain®	13(27%)	21(43%)	12(24%)	3(6%)

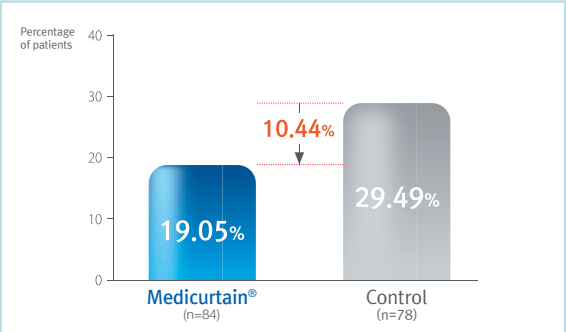
Method : Comparison of formation rates and grades of adhesion observed on the eighth week after laparoscopic surgery by laparoscopy, which was the first 2nd look procedure evaluated in Korea. (N=128)

Phase III Clinical Study : Thyroid Surgery

Results

Medicurtain® proved it is approximately 10% lower in adhesion incidence rate (19.05%) than the control group (24.49%)

1) Incidence of adhesions



PP Analysis group	Adhesion incidence rate	Adhesion incidence ratio difference	Confidence level upper limit (One-sided 97.5%)	P value‡
Medicurtain®	19.05% (16 patients / 84 patients)§	−10.44%†	2.71% Criterion:<9%)	0.0038
Control	29.49% (23 patients / 78 patients)§			

Method : Compared subjects who were scheduled to undergo thyroid surgery for the first time, 6 weeks after surgery to the Medicurtain® and control group. (N=162)

Clinical Trial Digest : Safety Summary

Results

- Based on the safety results, it is concluded that Medicurtain® is well tolerable and safe as a surgical adhesion barrier.
- According to the following clinical results below*, adverse events from the Medicurtain® group are not significant.

AE	Medicurtain® (112 patients)	Control (111 patients)	P-value**
Yes	17(15.18%)	10(9.01%)	0.1579 (Pearson Chi-square test)
No	95(84.82%)	101(90.99%)	

* Hysteroscopic Surgery ** P-value > 0.05 : not significant

Clinical Trial Efficacy and Safety Conclusion

- 5 clinical studies of Medicurtain® proved its superior efficacy in **hysteroscopic, laparoscopic, spinal, thyroid and nasal/sinus** surgeries in 680 patients.
- After safety analyses of 5 clinical studies, Medicurtain® is proven to be safe and well-tolerated through largest scale clinical studies.

Innovation of Surgical adhesion barrier

MEDICURTAIN®

CE 2265

Instruction for Use

Device Description

Adhesion is a scar tissue that binds two parts of tissue or organs should remain separated. It is developed when body immune system hyperactively produce fibrous tissue during natural wound healing process or blood coagulation responding to inflammation or surgery or trauma.
Post-surgical adhesion is frequently formed surgery. It often induces undesired complications including pelvic pain, infertility, pain or obstruction or spinal stenosis that may require additional treatment or intervention. In order to prevent the formation of post-surgical adhesion, it is recommended to use an anti-adhesion barrier which can remain at the site of application for long enough to prevent adhesion.
MEDICURTAIN is a sterile, nonpyrogenic, clear, viscoelastic, absorbable anti-adhesion barrier gel, composed of non-animal origin hyaluronic acid and hydroxyethylstarch in sterile water.
Hyaluronic Acid (HA) is a polysaccharide found in the most tissues and body fluids of vertebrates including human. Thus, it is a highly biocompatible and non-immunogenic substance. Hydroxyethylstarch (HES) is polysaccharide, well-tolerated blood plasma substitute used for preventing shock from blood loss by restoring blood volume.
HES has been widely used and its safety and toxicological effect are well-established.
MEDICURTAIN adheres to the tissue surface with mucoadhesive properties creating adhesion barrier which physically keeps the adjacent tissues separated during the healing process subsequent to a surgical procedure.
The efficacy and safety of MEDICURTAIN have been demonstrated in pre-clinical and clinical studies performed in abdominal, obstetric and spinal surgeries.
There are different volumes of MEDICURTAIN—1.2mL, 2mL, and 5mL— available to promote ease of use. It is pre-filled in a syringe which is provided sterile in a plastic tray with PE lid.
MEDICURTAIN is stable for 36 months when it is stored at 2-8℃.

Composition

Sodium Hyaluronate	10 mg/1mL
Hydroxyethylstarch	5mg/1mL
Sodium Chloride	8.5mg/1mL
Sodium phosphate, Dibasic	0.064mg/1mL
Water for Injection	1mL

Indication

MEDICURTAIN is intended to prevent or reduce the post- surgical adhesion formation after hysteroscopic, abdominal, spinal, thyroid and nasal/sinus surgeries.

Contraindication

MEDICURTAIN is contraindicated to use following patients
- if the wound area is infected or contaminated.
- if the patients having a known hypersensitivity to hyaluronic acid.
- Do not inject into blood vessels.

The safety and effectiveness of MEDICURTAIN has not been evaluated in following cases; therefore it is not recommended to use MEDICURTAIN in following patients.
- patients medicated with anticoagulants.
- diabetic patients medicated with oral or non-oral hypoglycemic agents.
- patients with autoimmune disease or immunodeficiency.
- patients with severe hepatic or renal diseases.
- The safety and efficacy of MEDICURTAIN in laparoscopic surgery or any procedures involving incision, excision, or resection of gastrointestinal or urinary tracts have not been established.

It is recommended to avoid being pregnant until the end of menstrual cycle after receiving MEDICURTAIN.
The safety and effectiveness of MEDICURTAIN in combination with other adhesion prevention products have not been established in clinical studies.

Precautions and Warnings

It should be stored at refrigerated temperature.
Do not use the product if package is opened or damaged.
Do not use the product if shelf life is expired.
Before injection into the peritoneal cavity, all irrigants in the surgical site should be aspirated.
Inject the product with aseptic technique.
Do not use with other anti-adhesion products.
It should be used immediately after opening the product and unused material must be discarded.
The product is for single use only.

Adverse Reactions

Injection procedures are associated with some adverse reactions in general, but not limited to: infection, allergic reaction, pain, and inflammatory reaction.

Direction For Use

Preparation

MEDICURTAIN must be administered by a qualified physician familiar with the procedure.
The patient should be informed about indication, expected results, contraindication, precautions and potential complications prior to the procedure.
Examine the package before use.
Examine the shelf life

Administration Procedure

Aspirate all irrigants in the surgical site.
Examine whether the surgical site is completely hemostatic.
Open the package in sterile condition. Remove tip cap of syringe and mount catheter tube onto the luer-lock of the syringe and lock it.
Administer sufficient amount of the product to cover the whole area.
Discard the unused material immediately.
Note: Do not reuse or re-sterilize the product. It is for single use only.

Shelf life and Storage

Expiry date is indicated on box. Store at 2 - 8℃.

Manufacturer

Shin Poong Pharm. Co., Ltd.
7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Korea

EC Representative

KTR Europe GmbH
Mergenthalerallee 77, 65760 Frankfurt/Eschborn, Germany

Symbols Used on Labels

No	Description	Symbol	Applied
1	Do Not Reuse		Outer box package, Blister Label, Instruction for Use
2	Batch Code	LOT	Outer box package, Syringe Label, Blister Label, Instruction for Use
3	Date of manufacture		Outer box package, Syringe Label, Blister Label, Instruction for Use
4	Use By		Outer box package, Syringe Label, Blister Label, Instruction for Use
5	Sterilization Using Ethylene Oxide	STERILE EO	Outer box package, Syringe Label, Blister Label, Instruction for Use
6	Caution, Consult Accompanying Documents		Outer box package, Blister Label, Instruction for Use
7	Manufacturer		Outer box package, Syringe Label, Blister Label, Instruction for Use
8	Authorized Representative in the European Community	EC REP	Outer box package Instruction for Use
9	Temperature Limitation (Store at 2-8℃)	2℃ 8℃	Outer box package Blister Label, Instruction for Use
10	Do not use if package is damaged		Outer box package Blister Label, Instruction for Use
11	Do not resterilize		Outer box package Blister Label, Instruction for Use
12	Consult Instructions For Use		Outer box package Blister Label, Instruction for Use

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SHIN POONG PHARM. CO., LTD.