





Vision

DESU has the 'vision' to become a leading manufacturer in medical sector with regard to the following principles; customer satisfaction, continuous development, quality, competitive pricing, team work, social responsibility, professional management, conformity to technological developments.

Mission

DESU has the mission to work in alignment with our vision and create resources and value for our customers, our staff and our country; in order to become a model in the medical sector.

Quality Certificates

Quality Certificates

Certificate of Full Quality Assurance

EC Design Examination Certificate

ISO 13485 Certificate

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DESU Medical manufacturing and R & D activities are performed in Class 10,000 and 1,000 clean room facilities within the Hacettepe University Technopark establishment.



Shunt Systems ●

Catheter Systems ●

Drainage Systems ●

Collagen Based Implant Systems ●

Shunt Systems

- Silicone Based Shunt Systems

A) DEFIT Shunts

1. *Defit Ultra Small (pediatric/infant) shunts (standard valve body / antibiotic impregnated valve body)*
2. *Defit Small shunts (standard valve body / antibiotic impregnated valve body)*
3. *Defit Regular (adult) shunts (standard valve body / antibiotic impregnated valve body)*

B) DECURVE Shunts

1. *Decurve Pediatric shunts (standard valve body / antibiotic impregnated valve body)*
2. *Decurve Adults shunts (standard valve body / antibiotic impregnated valve body)*

C) SILICONE BASED SHUNT KITS

1. *Defit Shunt Kits (standard / semi antibiotic impregnated / full antibiotic impregnated)*

- Polysulphone Based Shunt Systems

A) DEBUS Quick Response Shunts (standard valve body / antibiotic impregnated valve body)

B) DEBUS Quick Response Shunt Kits

1. *Standart Depus Quick Response Shunt Kits*
2. *Semi antibiotic impregnated Depus Quick Response Shunt Kits*
3. *Full antibiotic impregnated Depus Quick Response Shunt Kits*

- Shunt Accessories

1. *Desiphon Antisiphon Device*

* All shunt systems are supplied sterile (method: EO-Ethylene Oxide).

SILICONE BASED SHUNT SYSTEMS

All the silicone based valves are designed and manufactured using polypropylene and silicone elastomer, which decreases the possibility of deformation of the valves due to sticking. None of the valves contain any metal parts, which gives them the uniqueness of non-interference with MRI or CT scans. The radiopaque barium marks on the valves indicate pressure, flow direction and valve-to-catheter approximation. Moreover, all the valves are built in with a membrane valve mechanism and incorporated with reservoirs for percutaneous cerebrospinal fluid (CSF) access.

Moreover all the DESU valves have high technology version that contains antibiotics in the silicone body of the valves. Antibiotic impregnation of the silicone body is a one of a kind quality that none of the other valves in the market has. Controlled release of the impregnated antibiotics from the silicone body for a duration of 28 days is also the ultimate method for infection prevention, which is one of the main problems of shunt surgery.

DESU Medikal silicone shunt systems are manufactured and supplied in three pressure categories: low pressure, medium pressure, high pressure.

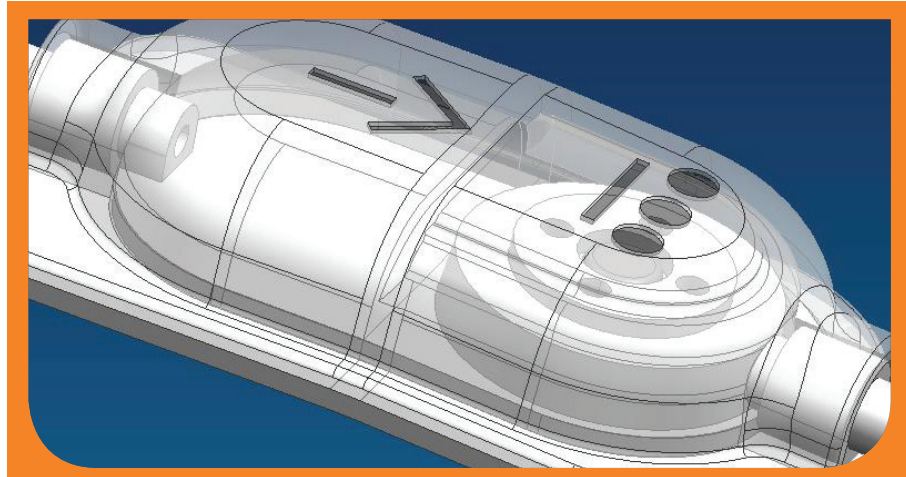
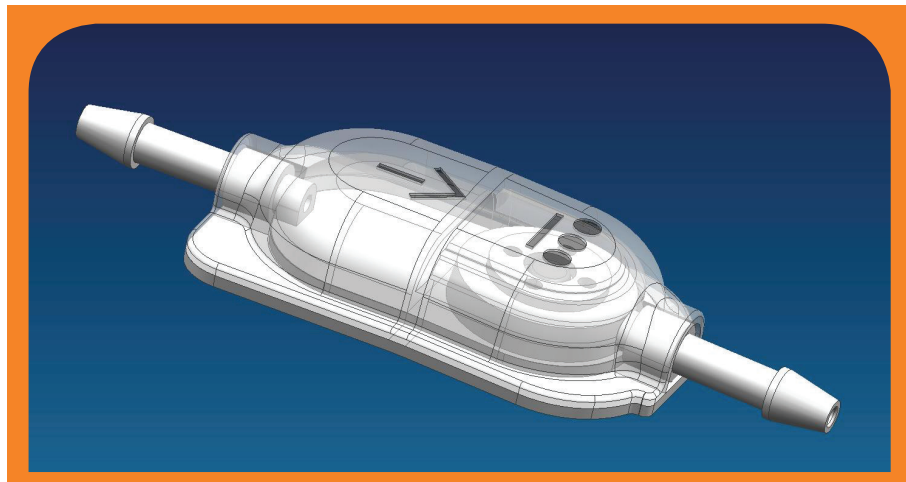
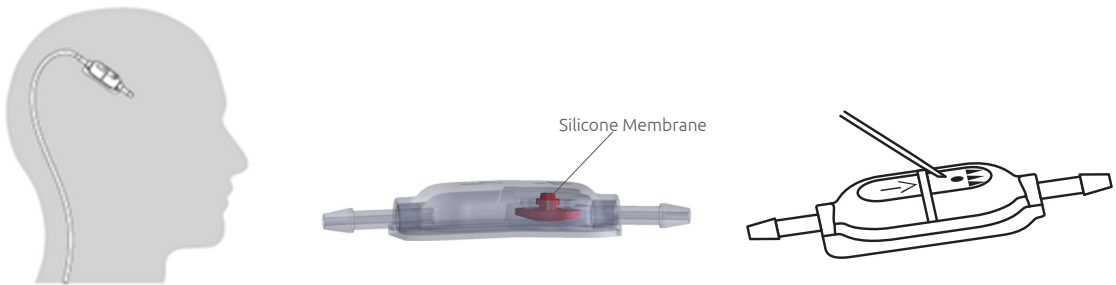
Pressure Levels	Standard Shunt Pressure Range (mm H ₂ O)	Shunt Marking
High pressure	110 - 180	•••
Medium pressure	50 - 110	••
Low pressure	10 - 50	•

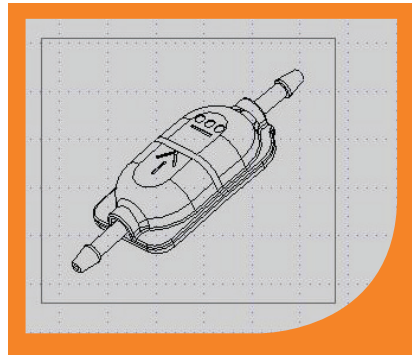
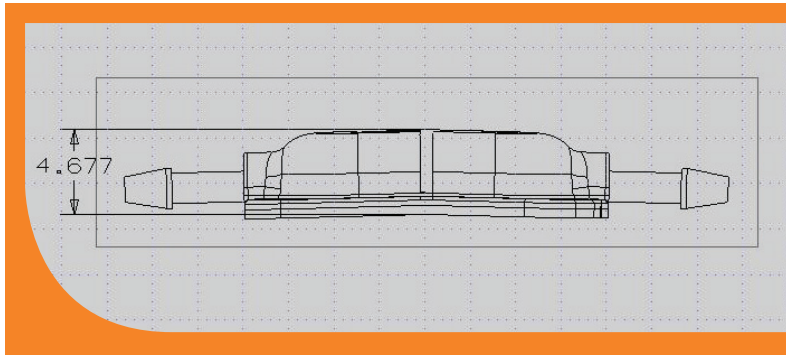
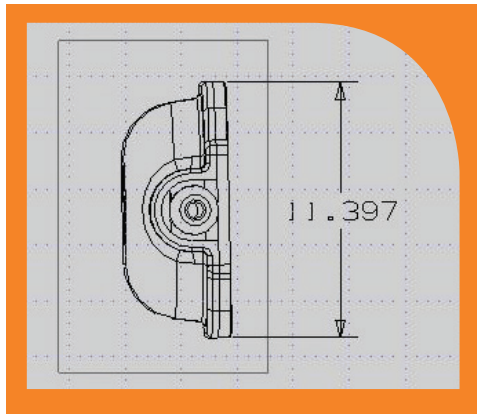
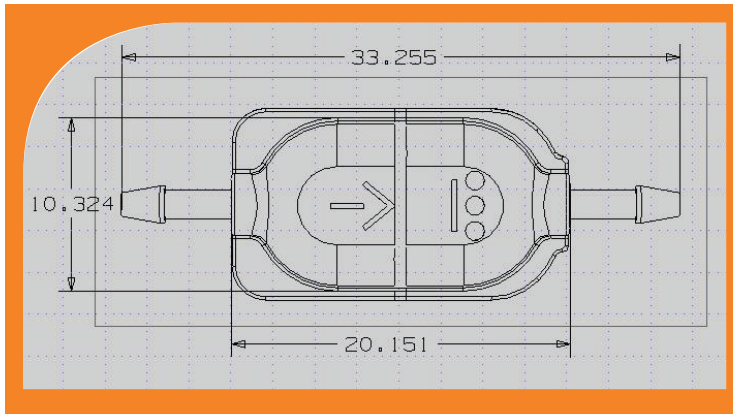
A) DEFIT SHUNTS

The shunt valve is a mechanical device that regulates flow. Regulation of flow, is attained through the simple fluid dynamics which requires a pressure drop of fluid while flowing through the obstacles like orifices and change of flow cross sectional area placed intentionally on the flow passage.

1. Defit Ultra Small (pediatric/infant) shunts (standard valve body / antibiotic impregnated valve body)

Defit Ultra Small shunts are used in infants and small children during treatment of hydrocephalus, where controlled drainage of CSF is required.





Standard Defit Ultra Small Shunts – Reference Codes according to Pressure Levels

●	●●	●●●
DFUS-L-PEB	DFUS-M-PEB	DFUS-H-PEB
Defit UltraSmall pediatric silicone shunt with reinforced base LOW PRESSURE	Defit UltraSmall pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Defit UltraSmall pediatric silicone shunt with reinforced base HIGH PRESSURE



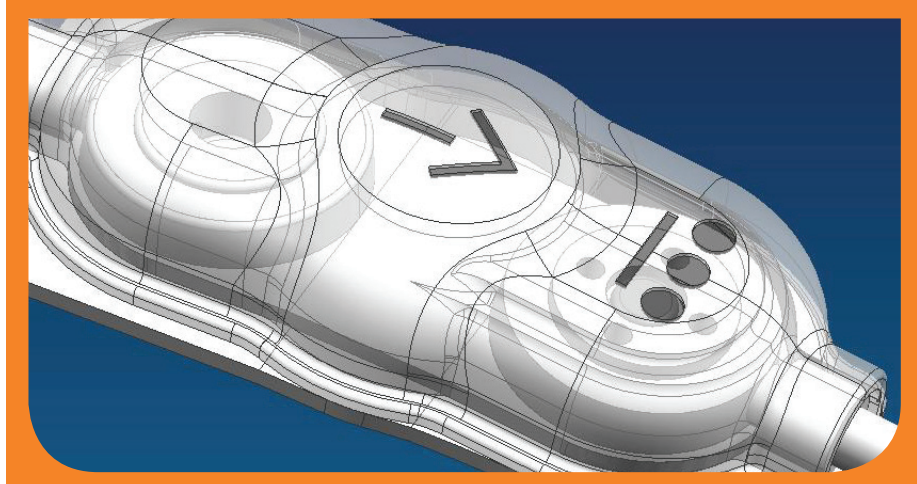
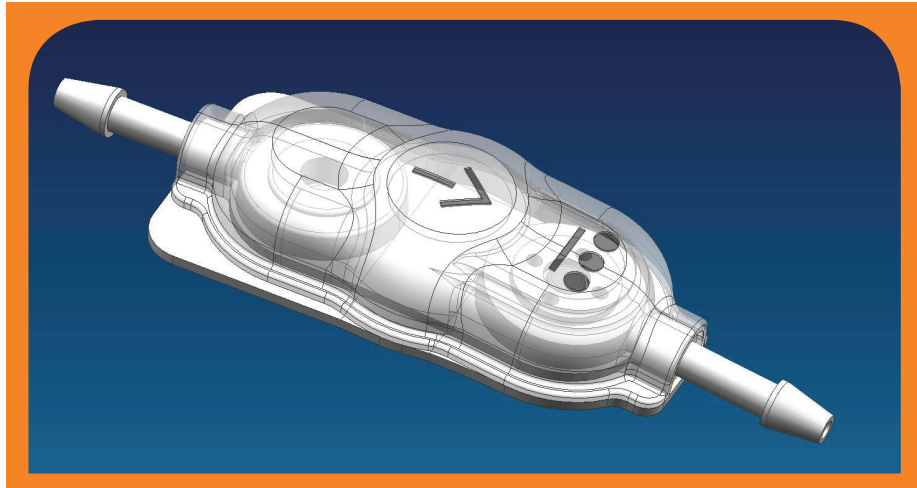
Antibiotic Impregnated Defit Ultra Small Shunts - Reference Codes according to Pressure Levels

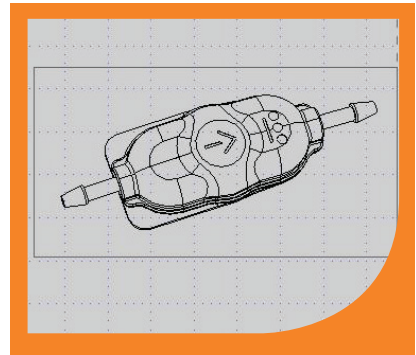
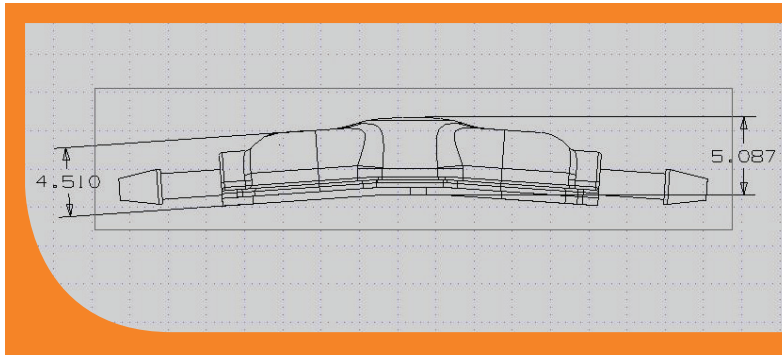
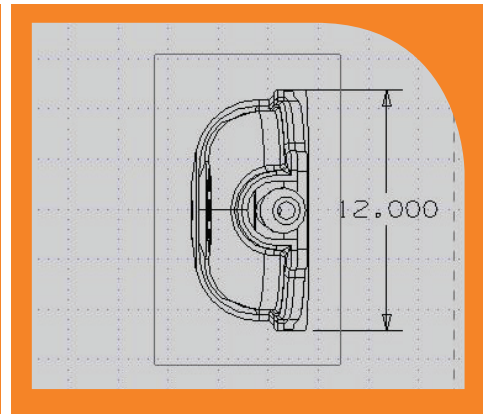
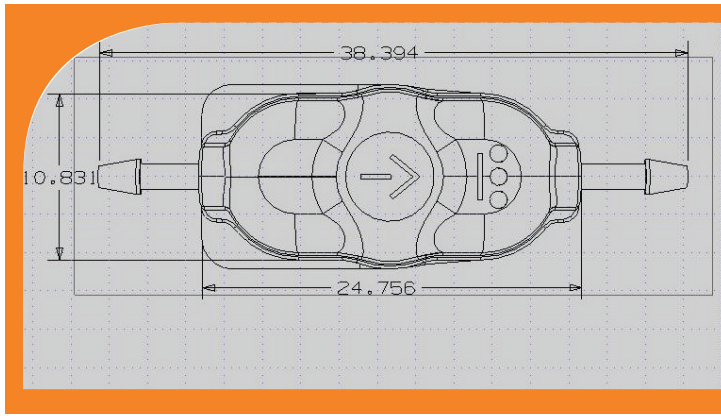
●	●●	●●●
ADFUS-L-PEB	ADFUS-M-PEB	ADFUS-H-PEB
Antibiotic Impregnated Defit UltraSmall pediatric silicone shunt with reinforced base LOW PRESSURE	Antibiotic Impregnated Defit UltraSmall pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Antibiotic Impregnated Defit UltraSmall pediatric silicone shunt with reinforced base HIGH PRESSURE



2. Defit Small shunts (standard valve body / antibiotic impregnated valve body)

Defit Small shunts are used in children and adults during treatment of hydrocephalus, where controlled drainage of CSF is required.





Standard Defit Small Shunts – Reference Codes according to Pressure Levels

•	••	•••
DFS-L-PEB	DFS-M-PEB	DFS-H-PEB
Defit Small pediatric silicone shunt with reinforced base LOW PRESSURE	Defit Small pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Defit Small pediatric silicone shunt with reinforced base HIGH PRESSURE



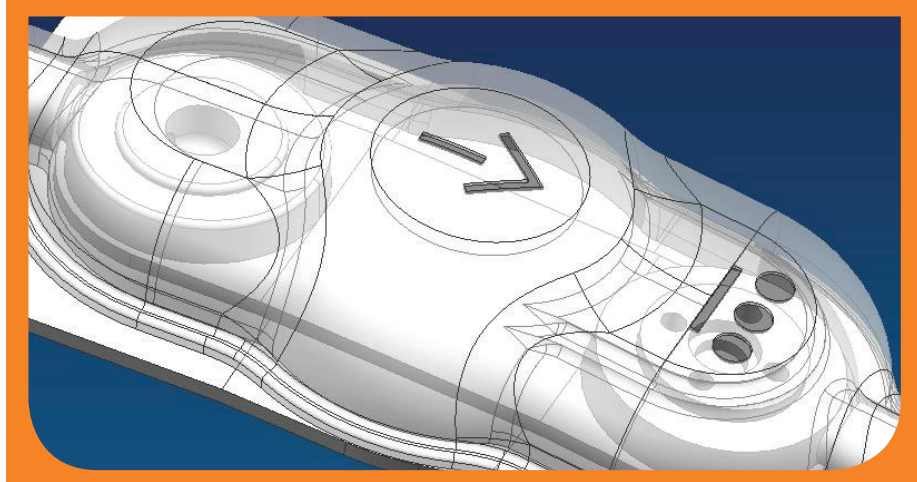
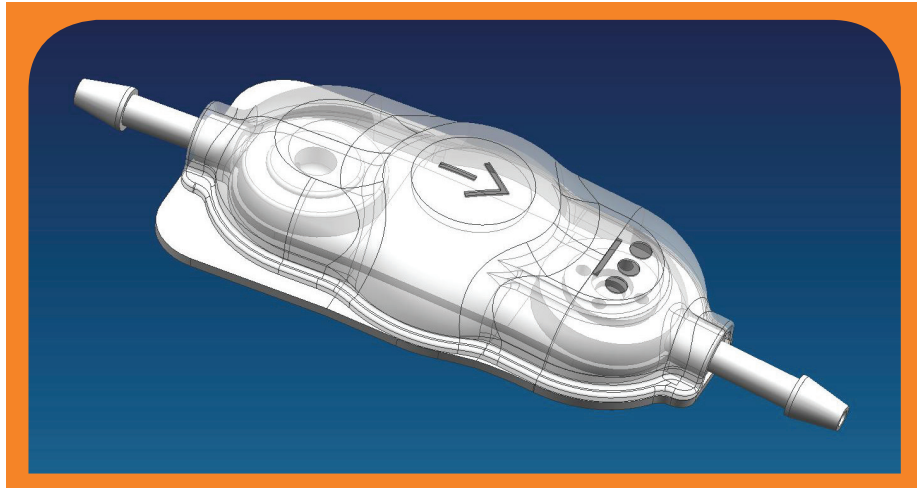
Antibiotic Impregnated Defit Small Shunts – Reference Codes according to Pressure Levels

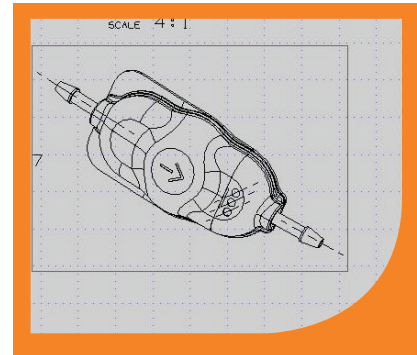
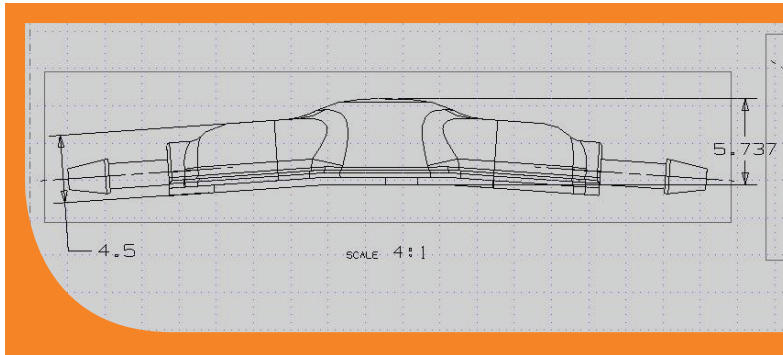
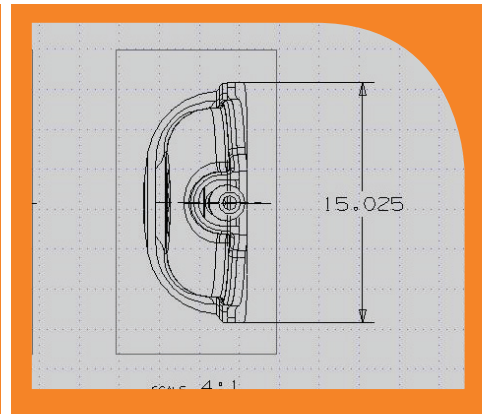
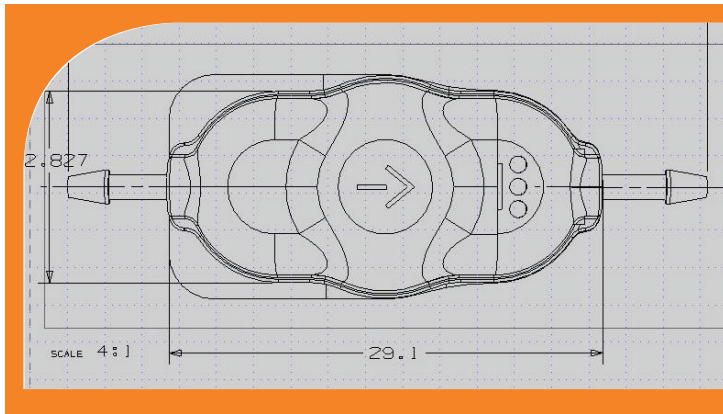
•	••	•••
ADFS-L-PEB	ADFS-M-PEB	ADFS-H-PEB
Antibiotic Impregnated Defit Small pediatric silicone shunt with reinforced base LOW PRESSURE	Antibiotic Impregnated Defit Small pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Antibiotic Impregnated Defit Small pediatric silicone shunt with reinforced base HIGH PRESSURE



3. Defit Regular (Adult) shunts (standard valve body / antibiotic impregnated valve body)

Defit Regular shunts are used in adults during treatment of hydrocephalus, where controlled drainage of CSF is required.





Standard Defit Regular Shunts – Reference Codes according to Pressure Levels

●	●●	●●●
DFR-L-PEB	DFR-M-PEB	DFR-H-PEB
Defit Regular pediatric silicone shunt with reinforced base LOW PRESSURE	Defit Regular pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Defit Regular pediatric silicone shunt with reinforced base HIGH PRESSURE



Antibiotic Impregnated Defit Small Shunts – Reference Codes according to Pressure Levels

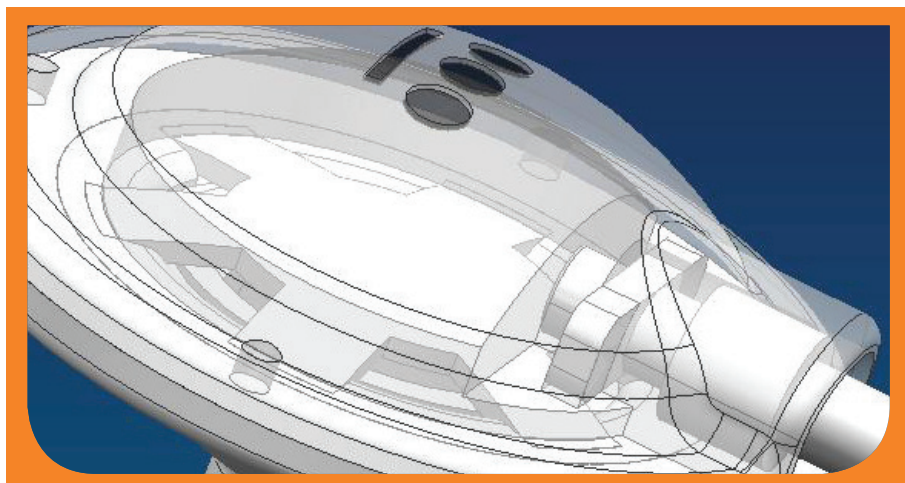
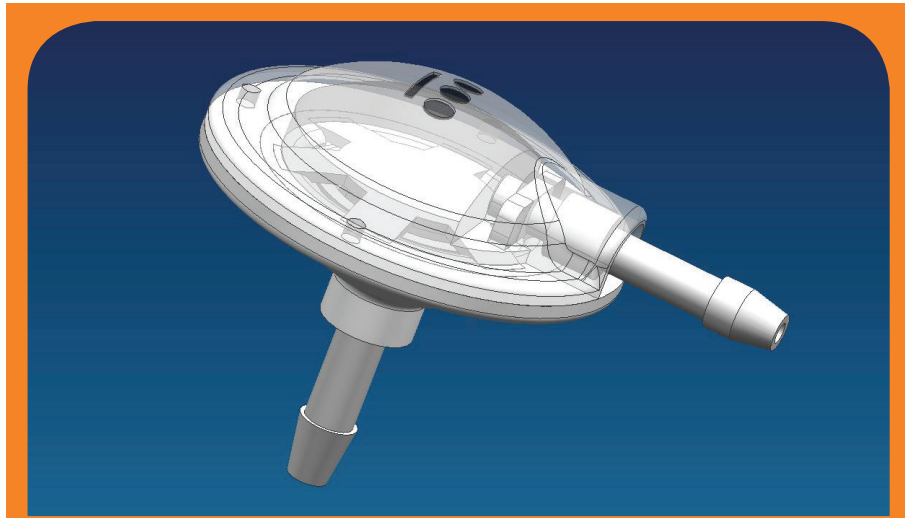
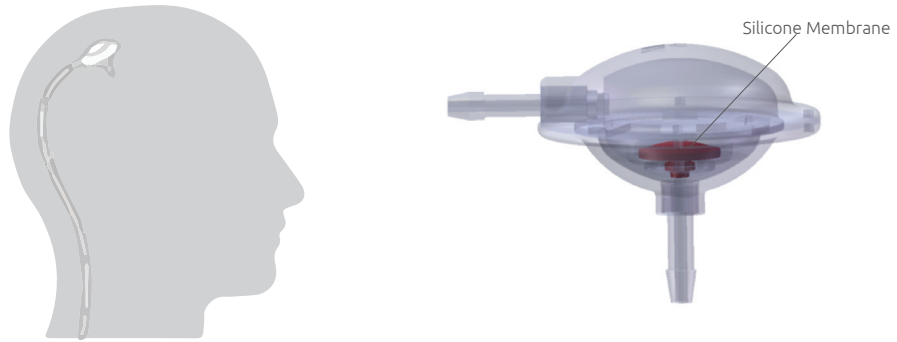
●	●●	●●●
ADFR-L-PEB	ADFR-M-PEB	ADFR-H-PEB
Antibiotic Impregnated Defit Regular pediatric silicone shunt with reinforced base LOW PRESSURE	Antibiotic Impregnated Defit Regular pediatric silicone shunt with reinforced base MEDIUM PRESSURE	Antibiotic Impregnated Defit Regular pediatric silicone shunt with reinforced base HIGH PRESSURE

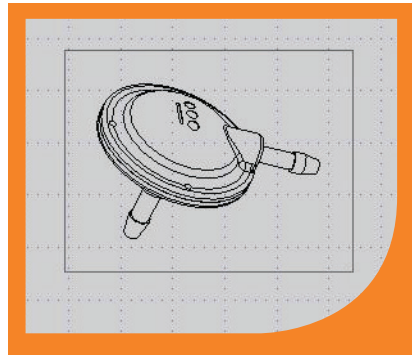
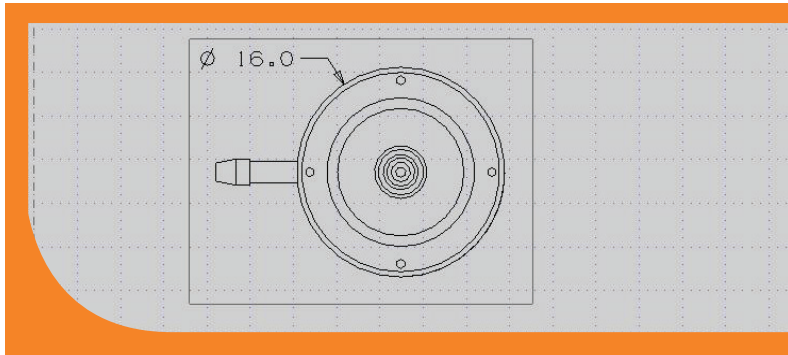
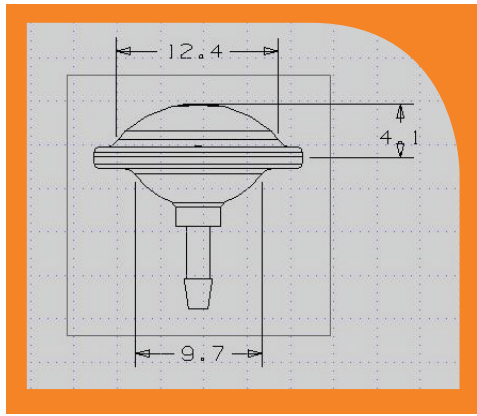
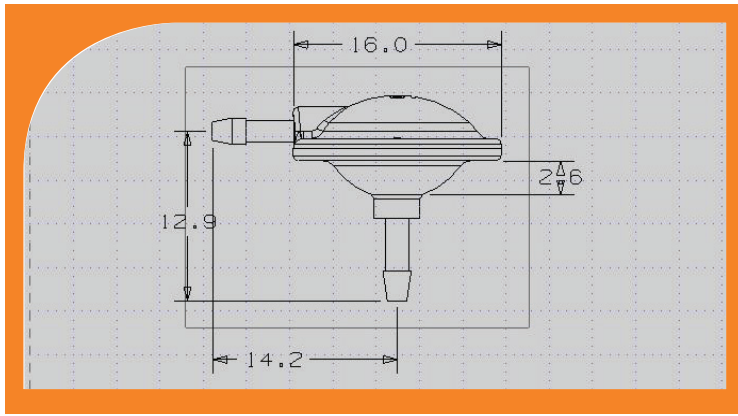


B) DECURVE SHUNTS

1. Decurve Pediatric Shunts (standard valve body / antibiotic impregnated valve body)

Decurve Pediatric shunts are used in infants and small children during treatment of hydrocephalus, where controlled drainage of CSF is required.





Standard Decurve Pediatric Shunts – Reference Codes according to Pressure Levels

● DCP-L	●● DCP-M	●●● DCP-H
Decurve Pediatric Silicone Shunt LOW PRESSURE	Decurve Pediatric Silicone Shunt MEDIUM PRESSURE	Decurve Pediatric Silicone Shunt HIGH PRESSURE



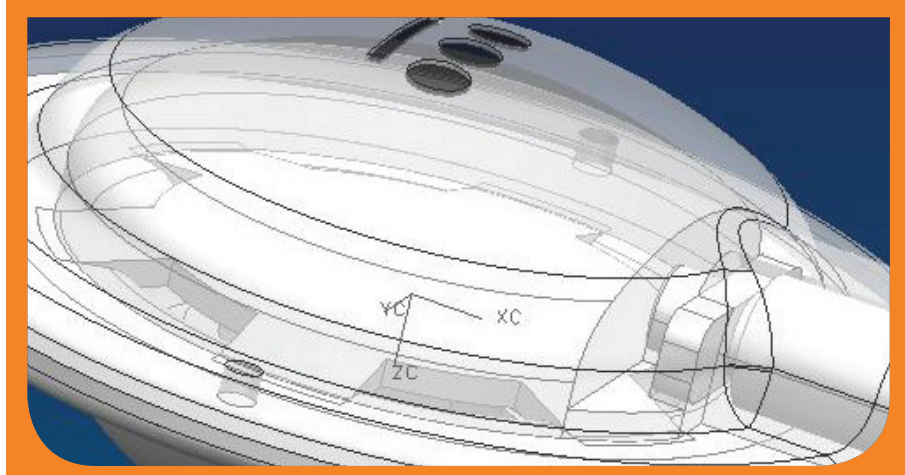
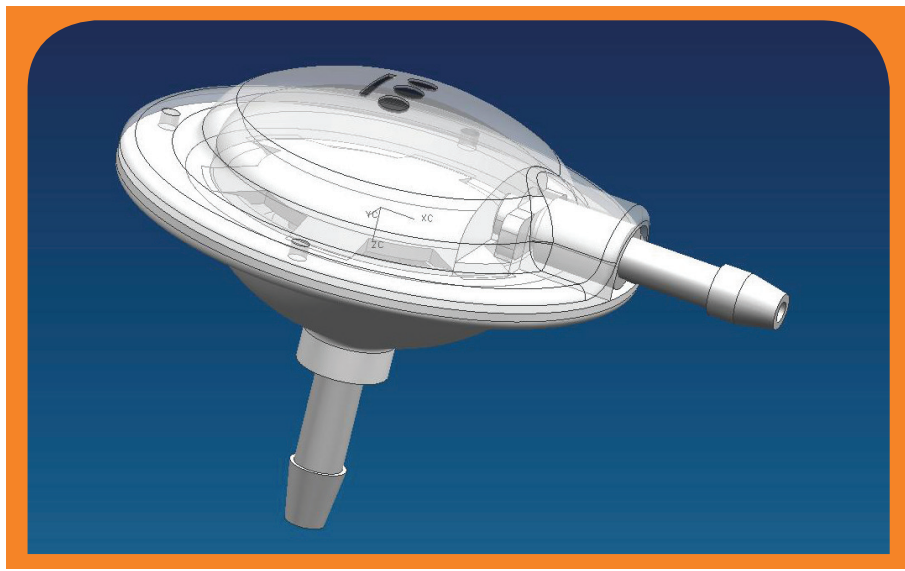
Antibiotic Impregnated Decurve Pediatric Shunts – Reference Codes according to Pressure Levels

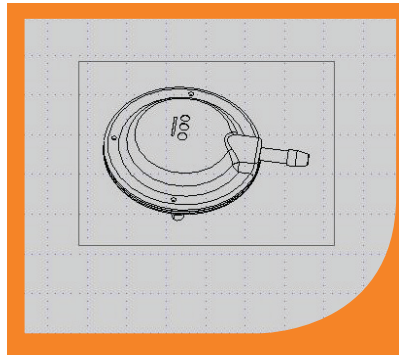
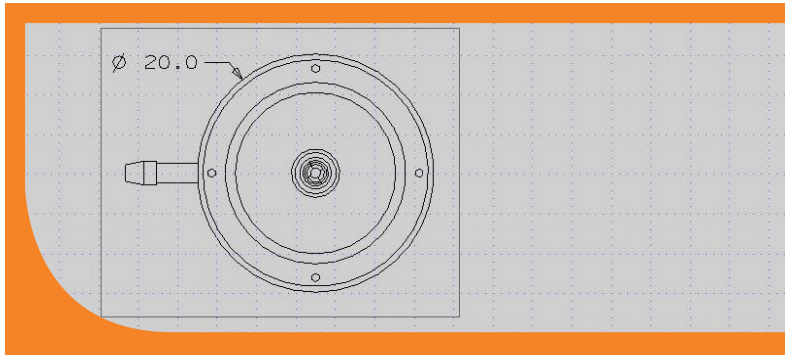
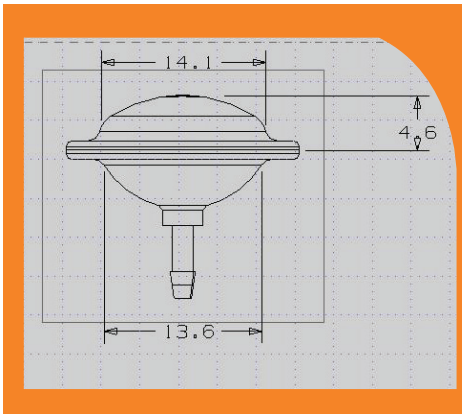
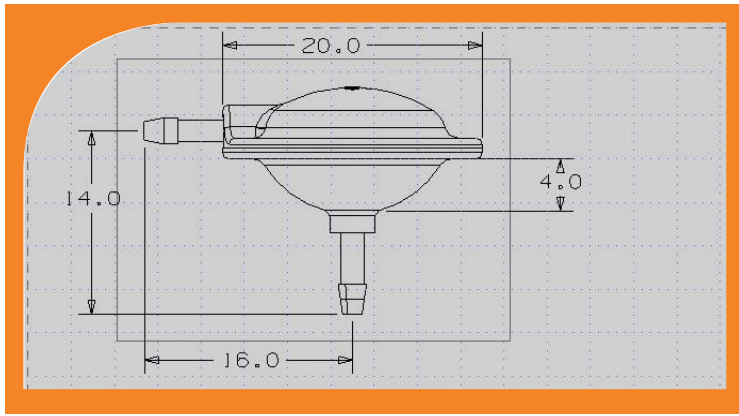
● ADCP-L	●● ADCP-M	●●● ADCP-H
Antibiotic Impregnated Decurve Pediatric Silicone Shunt LOW PRESSURE	Antibiotic Impregnated Decurve Pediatric Silicone Shunt MEDIUM PRESSURE	Antibiotic Impregnated Decurve Pediatric Silicone Shunt HIGH PRESSURE



2. Decurve Adult Shunts (standard valve body / antibiotic impregnated valve body)

Decurve Adult shunts are used in adults during treatment of hydrocephalus, where controlled drainage of CSF is required.





**Standard Decurve Adult Shunts
Reference Codes According to Pressure Levels**

● DCA-L	●● DCA-M	●●● DCA-H
Decurve Adult Silicone Shunt LOW PRESSURE	Decurve Adult Silicone Shunt MEDIUM PRESSURE	Decurve Adult Silicone Shunt HIGH PRESSURE



**Antibiotic Impregnated Decurve Adult Shunts
Reference Codes According to Pressure Levels**

● ADCA-L	●● ADCA-M	●●● ADCA-H
Antibiotic Impregnated Decurve Adult Silicone Shunt LOW PRESSURE	Antibiotic Impregnated Decurve Adult Silicone Shunt MEDIUM PRESSURE	Antibiotic Impregnated Decurve Adult Silicone Shunt HIGH PRESSURE

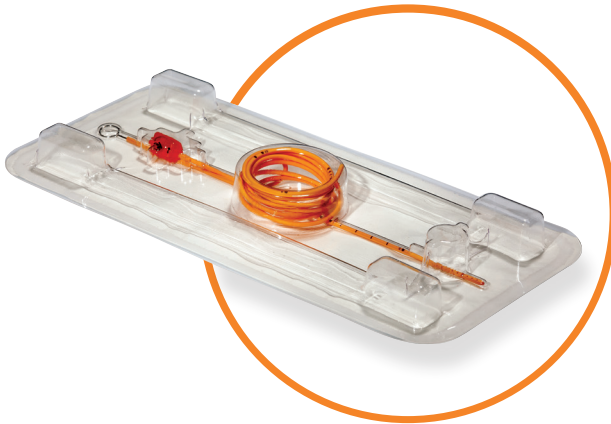


C) SILICONE BASED SHUNT KITS

1. Defit Shunt Kits (standard / semi antibiotic impregnated / full antibiotic impregnated)

Standard Defit Shunt Kit	Semi Antibiotic Impregnated Defit Shunt Kit	Full Antibiotic Impregnated Shunt Kit
<ul style="list-style-type: none"> ● Silicone outer shell and polypropylene inner body design ● MRI and CT compatible design that does not contain metal parts <ul style="list-style-type: none"> ● Radiopaque markings that show direction of flow and pressure level ● Reservoir design that allows CSF (cranial spinal fluid) sampling ● Ultrasmall, Small and Regular valve types 	<ul style="list-style-type: none"> ● Major advantage compared to Standard Defit Shunt kits, with antibiotic impregnated catheter content ● Wide spectrum of protection through joint impregnation of Clindamycin HCl and Rifampicin ● Prevention of bacteria colonization up to 28 years ● Low obstruction risk due to hydrophilic nature of catheters ● Ultrasmall, Small and Regular valve types 	<ul style="list-style-type: none"> ● Major advantage compared to Standard and Semi impregnated Defit Shunt kits, with antibiotic impregnated catheter and shunt body content ● Wide spectrum of protection through joint impregnation of Clindamycin HCl and Rifampicin ● Prevention of bacteria colonization up to 28 years ● Low obstruction risk due to hydrophilic nature of catheters ● Ultrasmall, Small and Regular valve types

Defit Ultrasmall Shunt Kits Reference Codes According To Pressure Levels



STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DFUS-L-VCK-PEB DFUS-M-VCK-PEB DFUS-H-VCK-PEB	DFUS-L-VACK-PEB DFUS-M-VACK-PEB DFUS-H-VACK-PEB	ADFUS-L-VACK-PEB ADFUS-M-VACK-PEB ADFUS-H-VACK-PEB
Defit Ultrasmall pediatric silicone shunt with reinforced base with Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Defit Ultrasmall pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Antibiotic impregnated Defit Ultrasmall pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE

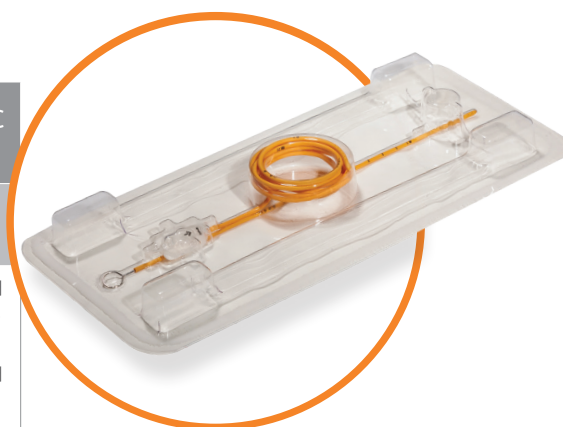
Defit Small Shunt Kits Reference Codes According To Pressure Levels

STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DFS-L-VCK-PEB DFS-M-VCK-PEB DFS-H-VCK-PEB	DFS-L-VACK-PEB DFS-M-VACK-PEB DFS-H-VACK-PEB	ADFS-L-VACK-PEB ADFS-M-VACK-PEB ADFS-H-VACK-PEB
Defit Small pediatric silicone shunt with reinforced base with Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Defit Small pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Antibiotic impregnated Defit Small pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE



Defit Regular Shunt Kits Reference Codes According To Pressure Levels

STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DFR-L-VCK-PEB DFR-M-VCK-PEB DFR-H-VCK-PEB	DFR-L-VACK-PEB DFR-M-VACK-PEB DFR-H-VACK-PEB	ADFR-L-VACK-PEB ADFR-M-VACK-PEB ADFR-H-VACK-PEB
Defit Regular pediatric silicone shunt with reinforced base with Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Defit Regular pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Antibiotic impregnated Defit Regular pediatric silicone shunt with reinforced base with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE



2. Decurve Shunt Kits (standard / semi antibiotic impregnated / full antibiotic impregnated)

Standard Defit Shunt Kit	Semi Antibiotic Impregnated Defit Shunt Kit	Full Antibiotic Impregnated Shunt Kit
<ul style="list-style-type: none"> ● Silicone outer shell and polypropylene inner body design ● MRI and CT compatible design that does not contain metal parts <ul style="list-style-type: none"> ● Radiopaque markings that show direction of flow and pressure level ● Reservoir design that allows CSF (crania spinal fluid) sampling ● 12 mm Pediatric and 16 mm Adult valve types 	<ul style="list-style-type: none"> ● Major advantage compared to Standard Defit Shunt kits, with antibiotic impregnated catheter content ● Wide spectrum of protection through joint impregnation of Clindamycin HCl and Rifampicin ● Prevention of bacteria colonization up to 28 years ● Low obstruction risk due to hydrophilic nature of catheters ● 12 mm Pediatric and 16 mm Adult valve types 	<ul style="list-style-type: none"> ● Major advantage compared to Standard and Semi impregnated Defit Shunt kits, with antibiotic impregnated catheter and shunt body content ● Wide spectrum of protection through joint impregnation of Clindamycin HCl and Rifampicin ● Prevention of bacteria colonization up to 28 years ● Low obstruction risk due to hydrophilic nature of catheters ● 12 mm Pediatric and 16 mm Adult valve types

Decurve Pediatric Shunt Kits – Reference Codes According To Pressure Levels



STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DCP-L-VCK DCP-M-VCK DCP-H-VCK	DCP-L-VACK DCP-M-VACK DCP-H-VACK	ADCP-L-VACK ADCP-M-VACK ADCP-H-VACK
Decurve Pediatric silicone shunt with Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Decurve Pediatric silicone shunt with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Antibiotic impregnated Decurve Pediatric silicone shunt with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE

Decurve Adult Shunt Kits – Reference Codes According To Pressure Levels



STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DCA-L-VCK DCA-M-VCK DCA-H-VCK	DCA-L-VACK DCA-M-VACK DCA-H-VACK	ADCA-L-VACK ADCA-M-VACK ADCA-H-VACK
Decurve Adult silicone shunt with Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Decurve Adult silicone shunt with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Antibiotic impregnated Decurve Adult silicone shunt with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE

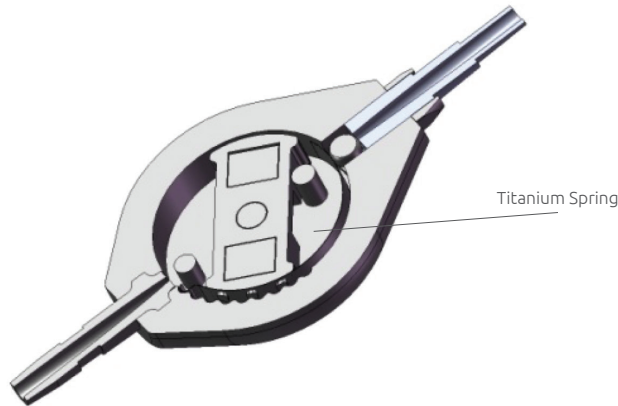
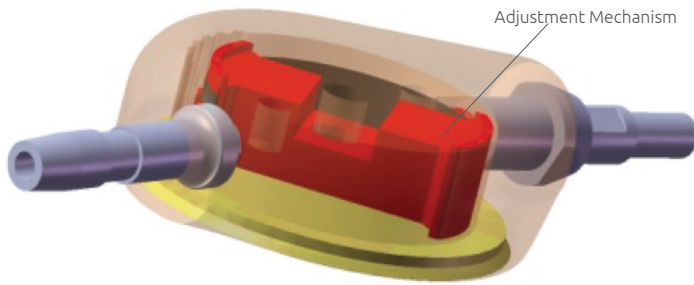
Polysulphone Based Shunt Systems

DESU DEPUS Quick Response shunt is designed to regulate and sustain the intra-ventricular pressure (IVP) of the patient via controlled drainage of the CSF (cerebrospinal fluid). The shunt has two versions according to intention of use: ventriculoperitoneal and lumboperitoneal.

The mechanism within the shunt is triggered by positive ventricular pressure and the valve opens immediately. The ruby ball and the titanium spring valve are the essentials of this adjustable system that works on the theory of hydrodynamic leverage.

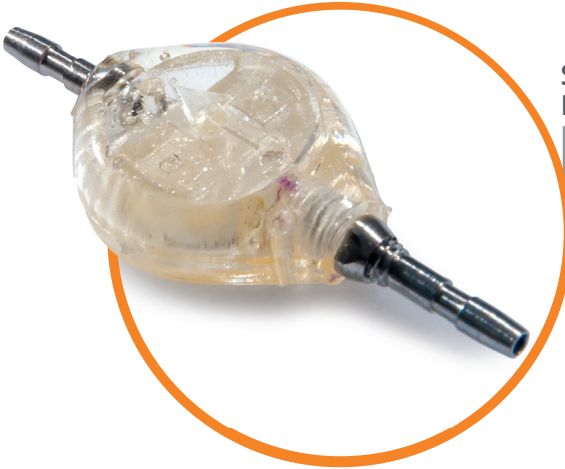
The shunt body is designed as to have uniquely smaller dimensions than its competitors. Inner diameter of the valve is 10 mm, outer diameter is 13,5 mm and the length is 16 mm.

DESU DEPUS Quick Response shunt is also designed with an infection-preventing version, which includes an antibiotic impregnated silicone cover. This antibiotic impregnated body design of the DEPUS valve is unique in the current shunt market. Controlled release of the impregnated antibiotics from the silicone body for 28 days is also the ultimate method for infection prevention, which is one of the main problems of shunt surgery.



A) DEPUS QUICK RESPONSE SHUNTS (STANDARD VALVE BODY / ANTIBIOTIC IMPREGNATED SILICONE COVER)

Polysulphone shunts are manufactured using radiopaque titanium, ruby ball and polysulphone (long term implantable) and are supplied sterile (ETO). The shunt pressure levels are marked with tantalum, which allows MRI visibility.



Standard Depus Quick Response Shunts Reference Codes According To Pressure Levels

●	●●	●●●
DP-L	DP-M	DP-H
Depus Quick Response Shunt LOW PRESSURE	Depus Quick Response Shunt MEDIUM PRESSURE	Depus Quick Response Shunt HIGH PRESSURE



Depus Quick Response Shunt With Antibiotic Impregnated Silicone Cover – Reference Codes According to Pressure Levels

●	●●	●●●
AADP-L	ADP-M	ADP-H
Depus Quick Response Shunt with Antibiotic impregnated silicone cover LOW PRESSURE	Depus Quick Response Shunt with Antibiotic impregnated silicone cover MEDIUM PRESSURE	Depus Quick Response Shunt with Antibiotic impregnated silicone cover HIGH PRESSURE

B) DEPUS QUICK RESPONSE SHUNT KITS

Standard Depus Quick Response Shunt Kits	Semi Antibiotic impregnated Depus Quick Response Shunt Kits	Full Antibiotic Impregnated Depus Quick Response Shunt Kits
<ul style="list-style-type: none"> ● Polysulphone body design enhanced with titanium spring and ruby ball ● MRI and CT compatible design that does not contain metal parts ● Tantalum markings to indicate direction of flow 	<ul style="list-style-type: none"> ● Major advantage compared to Standard Depus Quick Response shunts due to antibiotic impregnated catheters ● Wide spectrum of protection through joint impregnation of Clindamycin HCL and Rifampicin ● Prevention of bacteria colonization up to 28 days ● Low obstruction risk due to hydrophilic nature of catheters 	<ul style="list-style-type: none"> ● Antibiotic impregnated catheters and antibiotic impregnated silicone cover on valve body ● Wide spectrum of protection through joint impregnation of Clindamycin HCL and Rifampicin ● Prevention of bacteria colonization up to 28 days ● Low obstruction risk due to hydrophilic nature of catheters and shunt body

Depus Quick Response Shunt Kits – Reference Codes according to pressure levels

STANDARD	SEMI ANTIBIOTIC IMPREGNATED	FULL ANTIBIOTIC IMPREGNATED
DP-L-VCK DP-M-VCK DP-H-VCK	DP-L-VACK DP-M-VACK DP-H-VACK	ADP-L-VACK ADP-M-VACK ADP-H-VACK
Depus Quick Response Shunt with Ventriculoperitoneal Catheter Kit LOW-MEDIUM-HIGH PRESSURE	Depus Quick Response Shunt with Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE	Depus Quick Response Shunt with Antibiotic Impregnated silicone cover and Antibiotic impregnated Ventriculoperitoneal catheter kit LOW-MEDIUM-HIGH PRESSURE



Depus Quick Response Lumboperitoneal Shunt Kits – Reference Codes according to Pressure Levels

STANDARD	LUMBOPERITONEAL DEPUS QUICK RESPONSE SHUNT KIT
LPDP-L-LPCK LPDP-M-LPCK LPDP-H-LPCK	LPDP-L-LPACK LPDP-M-LPACK LPDP-H-LPACK
Depus Quick Response Lumboperitoneal shunt with Lumboperitoneal catheter kit and Polypropylene connector LOW – MEDIUM – HIGH PRESSURE	Depus Quick Response Shunt Lumbar Catheter Peritoneal Catheter



Shunt Accessories

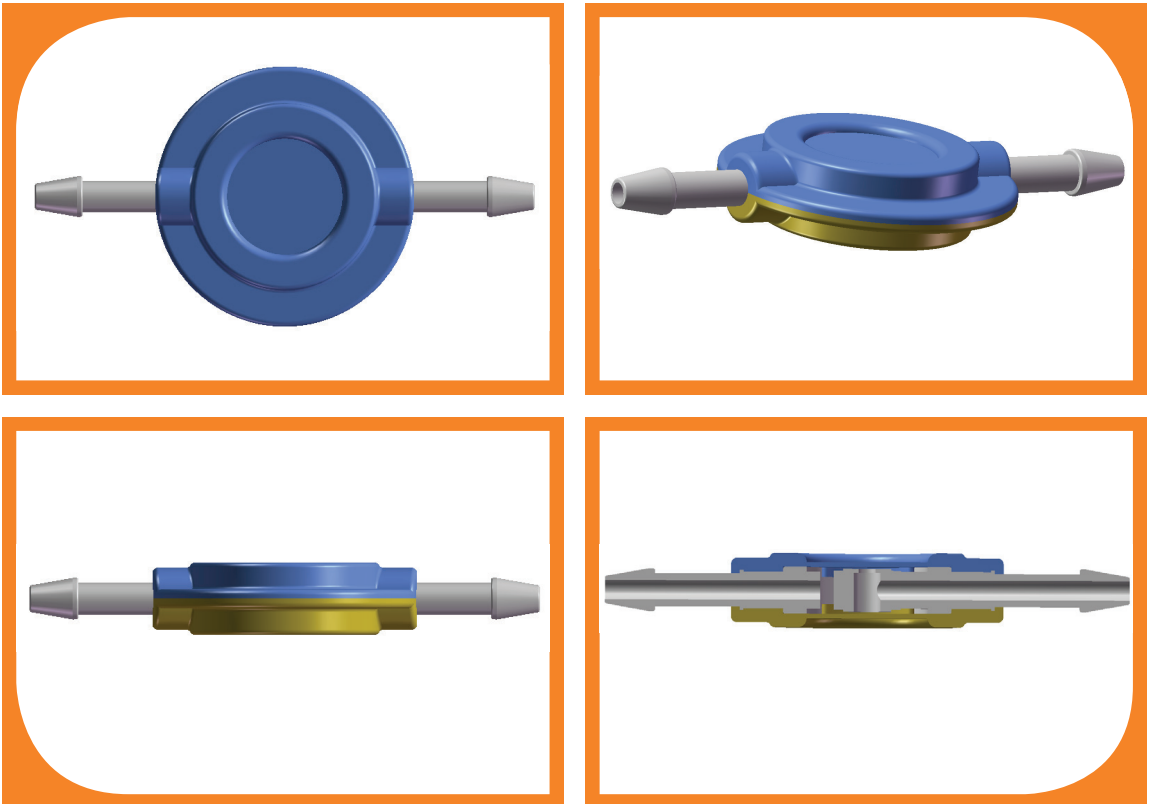
1. Desiphon Anti-siphon Device

Antisiphon is used to prevent the siphon effect, which might occur during hydrocephalus treatment when the CSF requires drainage or shunting and the peritoneal catheter's position suddenly changes from horizontal to vertical.

Major principle is to create a sudden closure effect in order to overcome the over-drainage that occurs under siphon effect.

Difference in Shunt pressure levels during antisiphon device use

CATEGORY	STANDARD SHUNT PRESSURE LEVELS (mmH ₂ O)	SHUNT PRESSURE LEVELS WHEN SHUNT IS USED TOGETHER WITH THE ANTISIPHON DEVICE (mmH ₂ O)
HIGH PRESSURE	110 – 180	135 – 210
MEDIUM PRESSURE	50 – 110	65 – 135
LOW PRESSURE	10 – 50	25 – 65



CATHETER SYSTEMS

- Catheters Types

- A) VENTRICULAR CATHETER (STANDARD / ANTIBIOTIC IMPREGNATED)
- B) PERITONEAL CATHETER (STANDARD / ANTIBIOTIC IMPREGNATED)
- C) VENTRICULOPERITONEAL CATHETER KIT (STANDARD / ANTIBIOTIC IMPREGNATED)
- D) EXTERNAL VENTRICULAR DRAINAGE CATHETER (STANDARD / ANTIBIOTIC IMPREGNATED)
- E) EXTERNAL LUMBAR DRAINAGE CATHETER (STANDARD / ANTIBIOTIC IMPREGNATED)
- F) LUMBAR CATHETER

- Catheter Accessories

- A) STILET
- B) TROCAR
- C) FIXATION TAB
- D) CONNECTORS
 - 1. Luer connector
 - 2. Right angle connector
 - 3. Straight connector
 - 4. L type connector
 - 5. Y type connector

* All catheter systems are supplied sterile (method: EO-Ethylene Oxide).

CATHETER TYPES

DESU® Catheter systems are used as a component of shunt systems indicated for use to drain or shunt the cerebrospinal fluid (CSF) in treatment of hydrocephalus. All DESU Catheters are manufactured with barium impregnated silicone raw material to allow radiopacity. In addition, tantalum is used to mark the length measurements on the catheters, which allows visibility during magnetic resonance imaging (MRI).

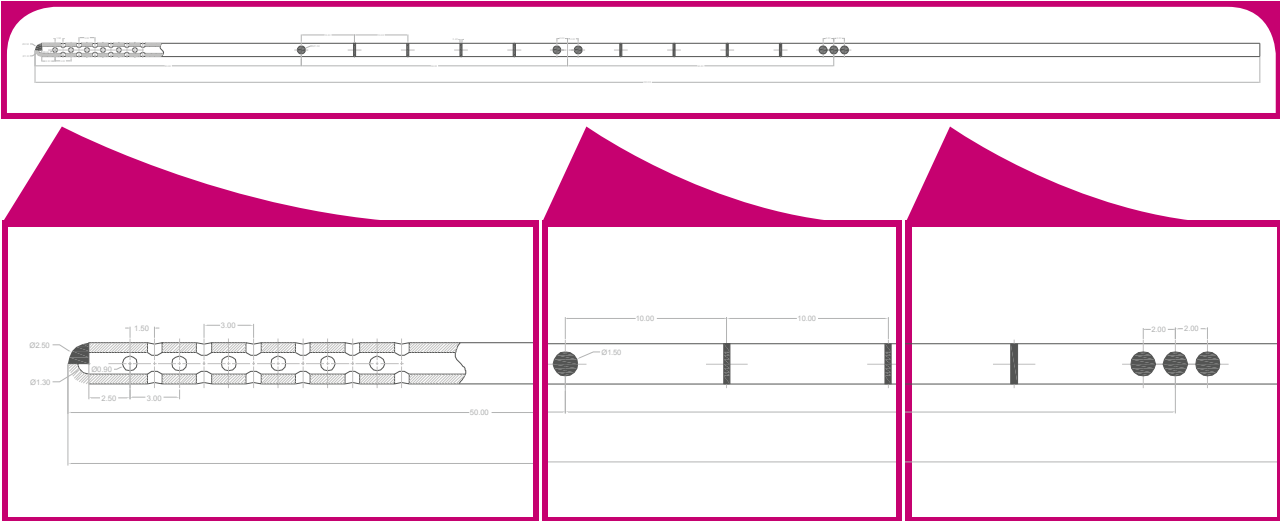
Antibiotic impregnated catheters (barium impregnated) are manufactured using long-term implantable grade silicone tubing. The catheters, which are impregnated with Rifampicin and Clindamycin HCl, are shown to decrease gram-positive bacteria colonization.

Length and Inner and Outer Diameter Measurements of the Catheters

CATHETER TYPE	LENGTH (CM)	INNER DIAMETER / OUTER DIAMETER (MM)
VENTRICULAR CATHETER	23	1.3 / 2.5
PERITONEAL CATHETER	120	1.1 / 1.3
EXTERNAL VENTRICULAR CATHETER	31	1.5 / 3
EXTERNAL LUMBAR CATHETER	80	0.8 / 1.6
LUMBAR CATHETER	105	0.8 / 1.6

A) VENTRICULAR CATHETER (STANDARD / ANTIBIOTIC)

Ventricular catheter is used to transfer excess CSF (cerebrospinal fluid) from the brain ventricles to the shunt. Ventricular catheter length is 23 cm. Inner diameter of the catheter is 1.3 mm and outer diameter is 2.5 mm. Tantalum is used to mark the length measurements on the catheters on 5, 10 and 15 cm points.



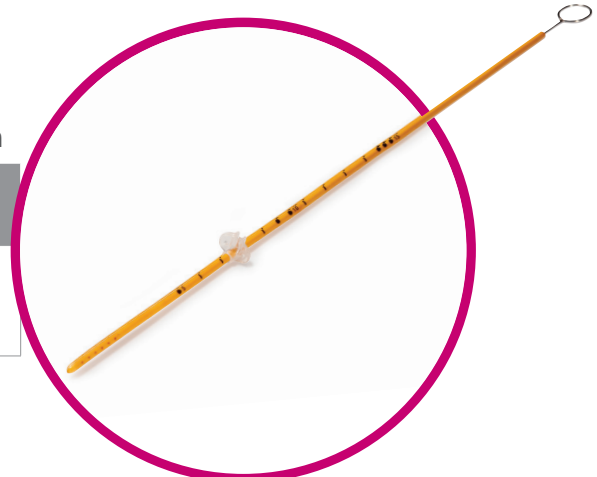
Standard Ventricular Catheter System

PRODUCT CODE	PRODUCT NAME
SVCK	Standard Ventricular Catheter



Antibiotic impregnated Ventricular Catheter System

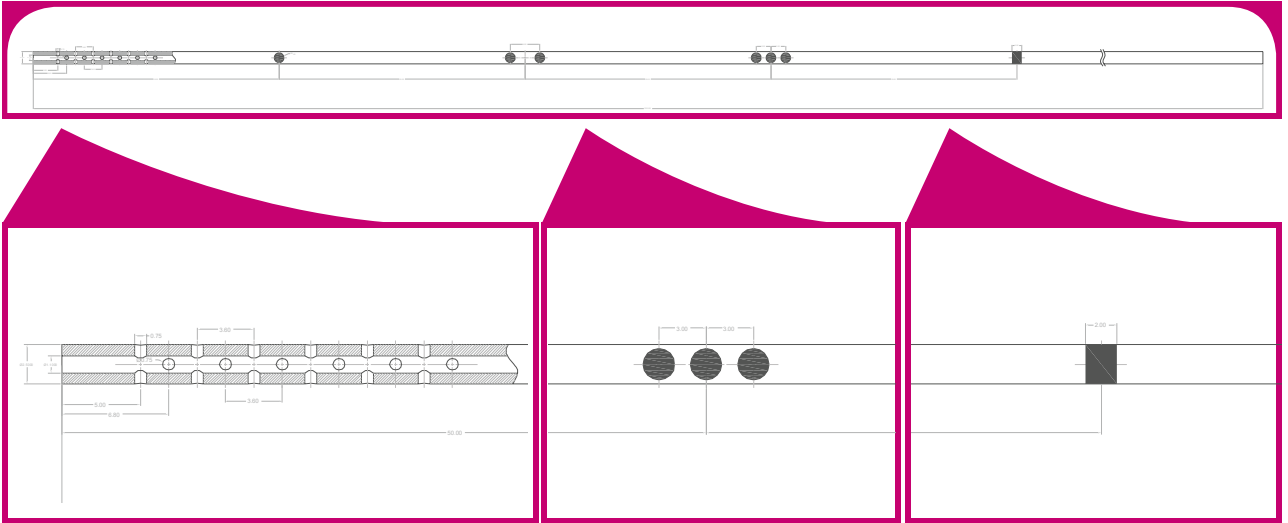
PRODUCT CODE	PRODUCT NAME
ASVCK	Antibiotic Impregnated Catheter



B) PERITONEAL CATHETER (STANDARD / ANTIBIOTIC IMPREGNATED)

Peritoneal catheter is used to transfer excess CSF, that is drained with a controlled pressure from the ventricles by the use of ventriculoperitoneal shunt.

Peritoneal catheter length is 120 cm. Inner diameter of the catheter is 1.1 mm and outer diameter is 1.3 mm. Tantalum is used to mark the length measurements on the catheters on 5, 10, 15 and 20 cm points.



Standard Peritoneal Catheter System

PRODUCT CODE	PRODUCT NAME
SPCK	Peritoneal distal catheter – closed tip

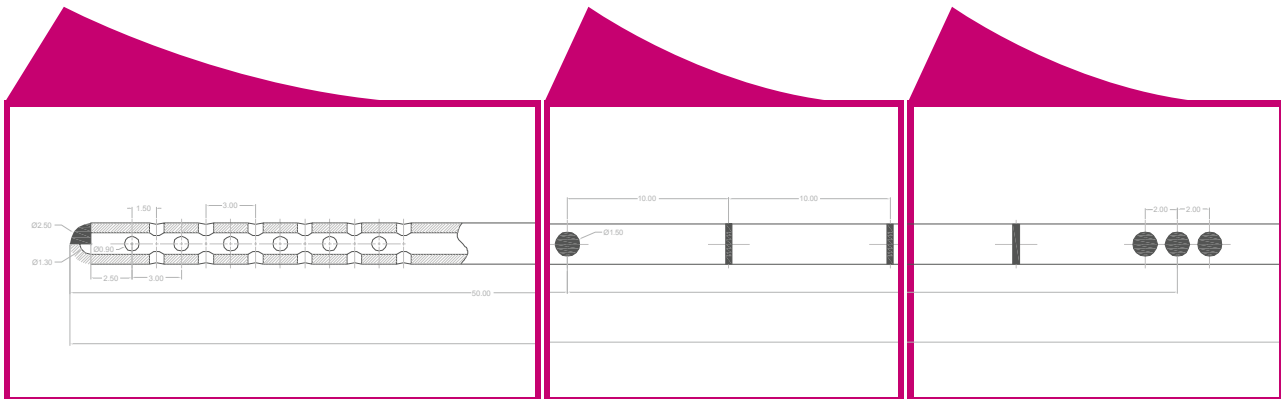
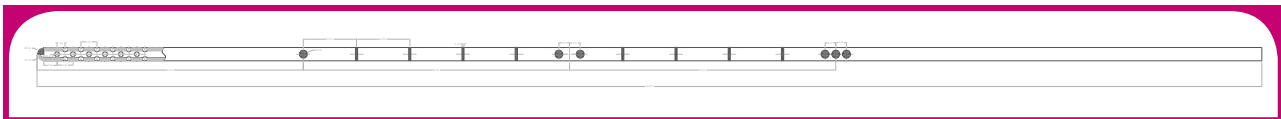


Antibiotic Impregnated Peritoneal Catheter System

PRODUCT CODE	PRODUCT NAME
ASPK	Antibiotic impregnated distal catheter – closed tip

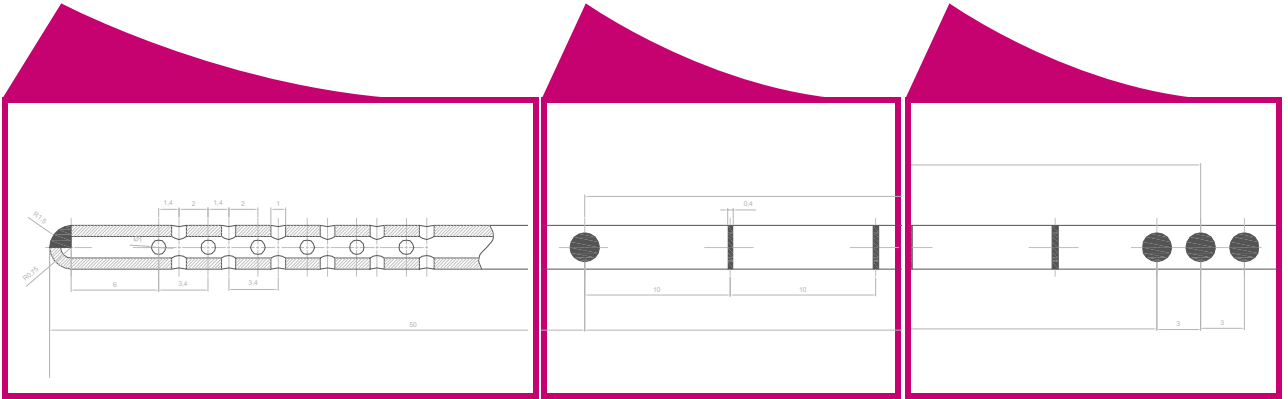
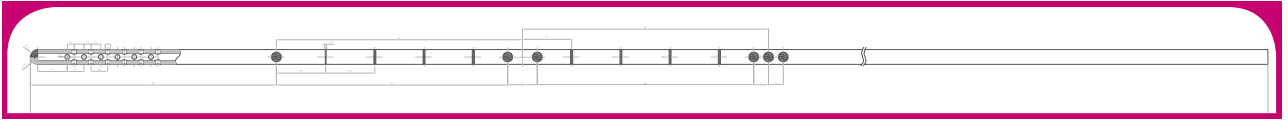
C) VENTRICULOPERITONEAL CATHETER KIT (STANDARD / ANTIBIOTIC IMPREGNATED)

Standard Ventriculoperitoneal Catheter Kit	Antibiotic Impregnated Ventriculoperitoneal Catheter Kit
<ul style="list-style-type: none"> ● Barium impregnated radiopaque silicone material ● Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings ● 24 entry holes at the proximal tip to avoid obstruction 	<ul style="list-style-type: none"> ● Barium impregnated radiopaque silicone material ● Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings ● 24 entry holes at the proximal tip to avoid obstruction ● Antibacterial protection for 28 days, through impregnation of Rifampicin and Clindamycin HCL. ● Colonization and obstruction preventing inner and outer surface through hydrophilic characteristic ● (0.054%) Rifampicin and (0.15%) Clidamycin HCL content ● Antibiotic dose suitable for pediatric use



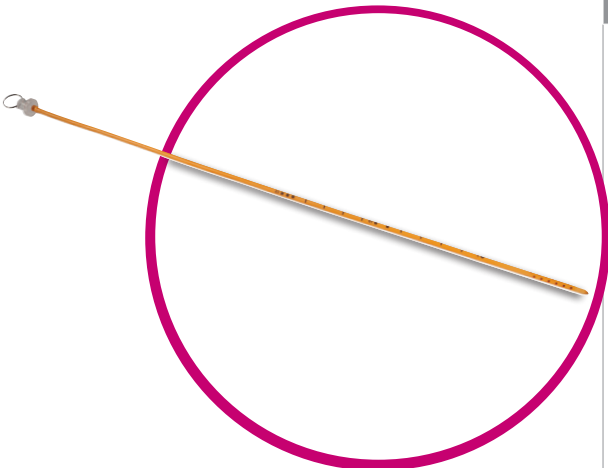
D) EXTERNAL VENTRICULAR DRAINAGE CATHETER KIT (STANDARD / ANTIBIOTIC IMPREGNATED)

External Ventricular Drainage Catheter is the main component of the External Neurological Drainage System and is used to drain excess CSF from the brain ventricles and transfer it to the drainage system.



Standard EVD Catheter System

PRODUCT CODE	PRODUCT NAME	PRODUCT PROPERTIES
EVDCK	External Ventricular Drainage Catheter System	<ul style="list-style-type: none"> • Barium impregnated radiopaque silicone material • Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings • 24 entry holes at the proximal tip to avoid obstruction • Kit system including trocar, stylet, luer connector and fixation tab

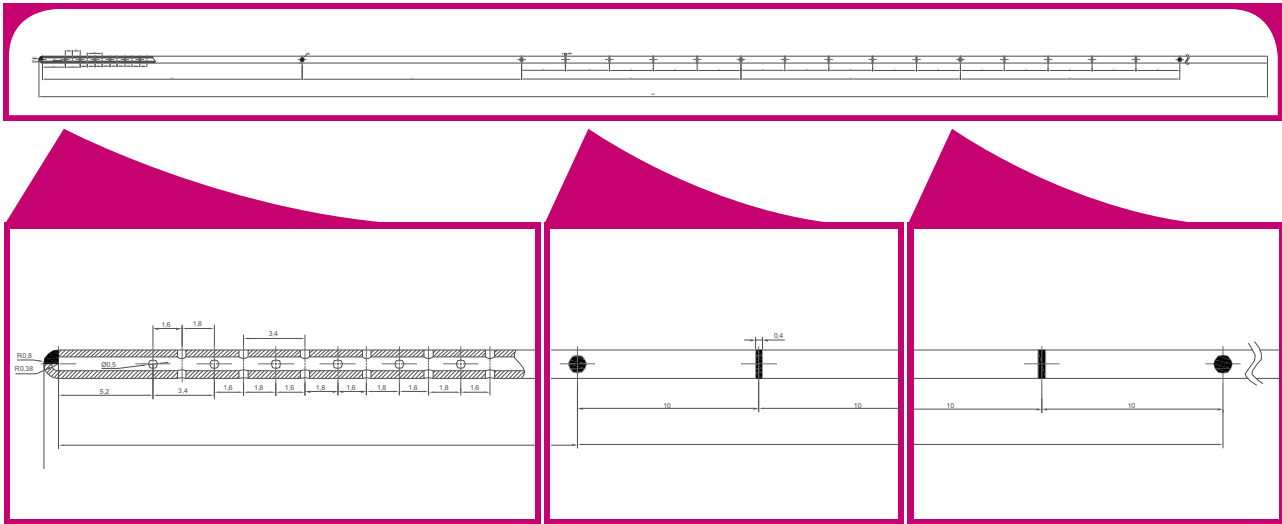


Antibiotic Impregnated EVD Catheter System

PRODUCT CODE	PRODUCT NAME	PRODUCT PROPERTIES
EVDACK	Antibiotic Impregnated External Ventricular Drainage Catheter System	<ul style="list-style-type: none"> • Barium impregnated radiopaque silicone material • Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings <ul style="list-style-type: none"> • 24 entry holes at the proximal tip to avoid obstruction • Antibacterial protection for 28 days, through impregnation of Rifampicin and Clindamycin HCl on the catheter • Colonization and obstruction preventing inner and outer surface through hydrophilic characteristic <ul style="list-style-type: none"> • (0.054%) Rifampicin and (0.15%) Clindamycin HCl content • Antibiotic dose suitable for pediatric use • Kit system including trocar, stylet, luer connector and fixation tab

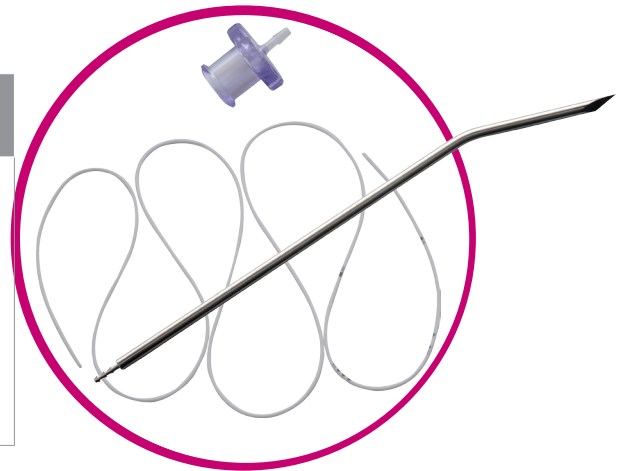
E) EXTERNAL LUMBAR DRAINAGE CATHETER

External Lumbar Drainage Catheter is the main component of the External Neurological Drainage System and is used to drain excess CSF from the lumbar subarachnoid cavity and transfer it to the drainage system.



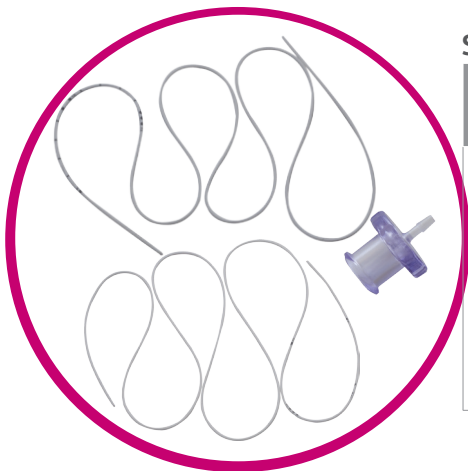
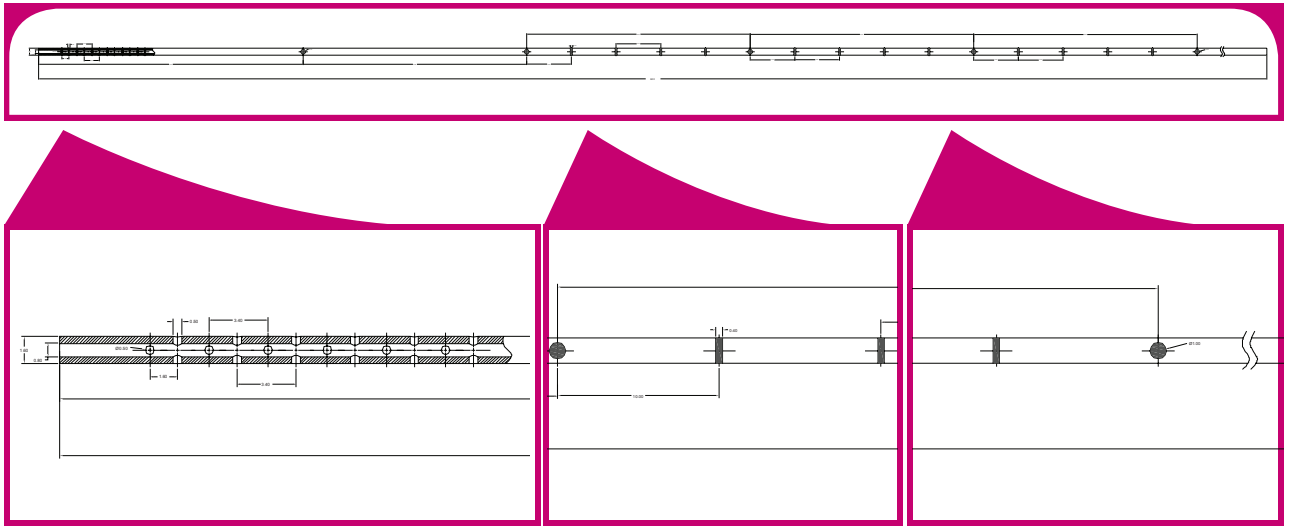
Standard Lumbar Drainage Catheter System

PRODUCT CODE	PRODUCT NAME	PRODUCT PROPERTIES
ELCK	External Lumbar Drainage Catheter System	<ul style="list-style-type: none"> • Barium impregnated radiopaque silicone material • Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings • 24 entry holes at the proximal tip to avoid obstruction • Kit system including trocar, stylet, luer connector and fixation tab



F) LUMBAR CATHETER (STANDARD)

Lumbar catheter is one of the components of the lumboperitoneal catheter kit within the lumboperitoneal shunt system. Lumboperitoneal catheter kit consists of lumbar catheter and peritoneal catheter. Lumbar catheter is used to transfer excess CSF from the subarachnoid cavity to the shunt; while the shunt delivers the CSF with a pre-arranged pressure level to the peritoneal cavity.



Standard Lumboperitoneal Catheter System

PRODUCT CODE	PRODUCT NAME	PRODUCT PROPERTIES
LPCK	Lumbo Peritoneal Catheter System	<ul style="list-style-type: none"> • Barium impregnated radiopaque silicone material • Magnetic Resonance Imaging (MRI) visibility through the use of tantalum markings • 24 entry holes at the proximal tip to avoid obstruction • Lumboperitoneal catheter system with lumbar catheter and peritoneal catheter

CATHETER ACCESSORIES

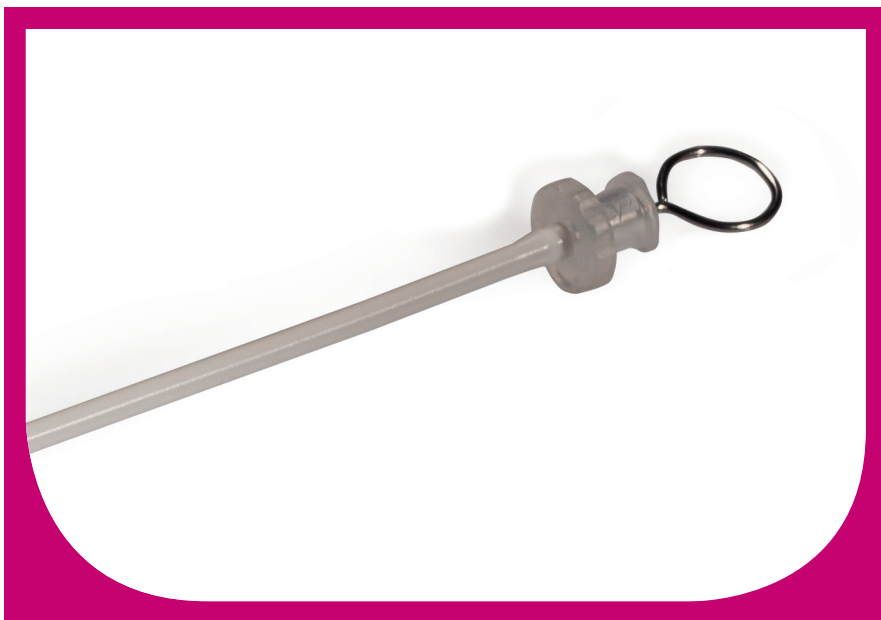
A) STYLET

Stylet is used to transfer the catheter to the brain ventricle during catheterization of the ventricular shunt catheter or external ventricular drainage catheter.

Stylet used for Ventricular Catheter



Stylet used for External Ventricular Drainage Catheter



B) TROCAR

Trocar is used for the transfer of the external ventricular catheter under the tissue during catheterization.



Note: trocar with the thinner connection tip is used with the external lumbar drainage system; while trocar with the thicker connection tip is used with the external ventricular drainage system.

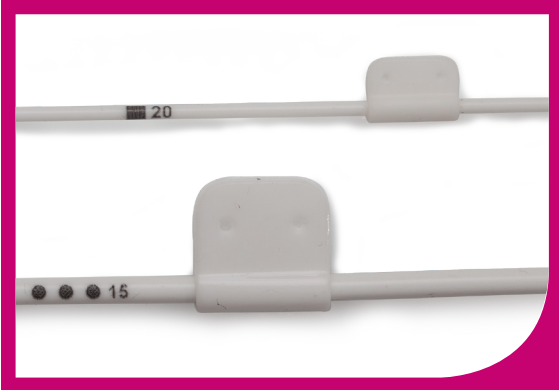
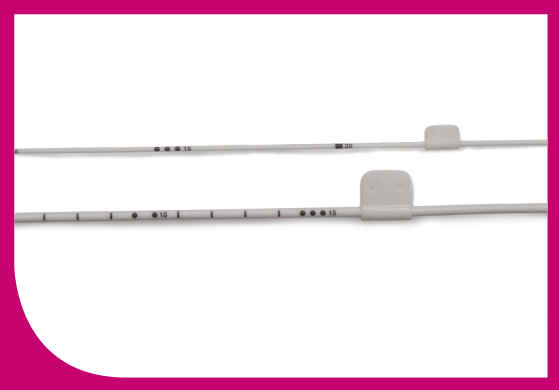
C) FIXATION TAB

Fixation tab is an aiding device that is used to fix the External Ventricular Drainage Catheter and the External Lumbar Drainage Catheter.

EVD Catheter Fixation Tab



External Lumbar Catheter Fixation Tab



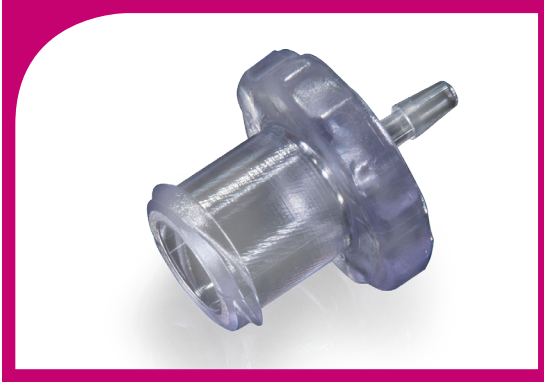
Fixation Tab Use

D) CONNECTORS

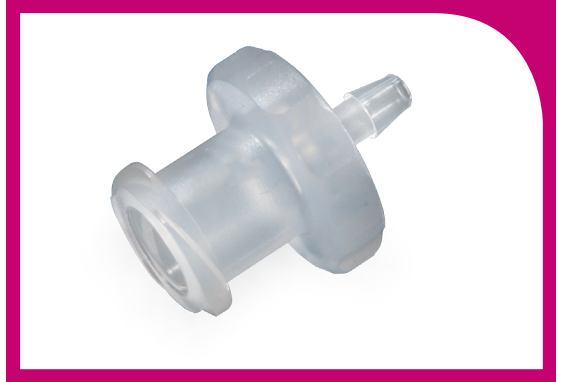
1. Luer Connector

- Luer connector is an aiding device that is used to connect the External Ventricular Drainage Catheter / External Lumbar Catheter to the External Neurological Drainage System (ENDS).

Lumbar Drainage Luer Connector



EVD Luer Connector



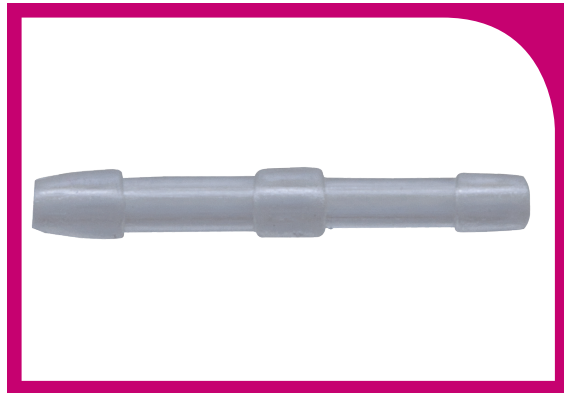
2 Right Angle Connector

Right angle connector is an aiding device that is used to change the direction of the Ventricular catheter, when needed during surgery, without causing bending or obstruction.



3. Straight Connector

Straight connector is an aiding device that is used to connect different catheter pieces to each other during surgery.



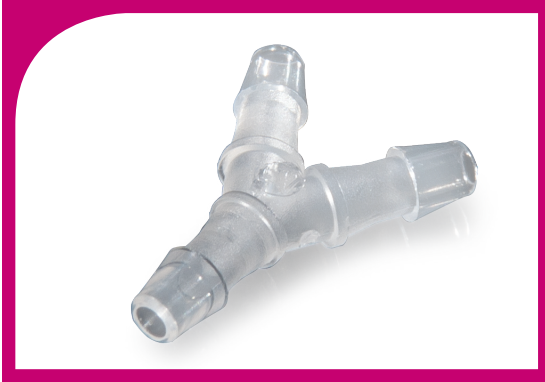
4. L Type Connector

L type connector is used to change the direction of the Ventricular / Peritoneal Catheter and/or connect different catheter pieces to each other, during surgery when needed, without causing bending or obstruction.



5. Y Type Connector

Y connector is used in one of the following conditions: to connect two shunts to one peritoneal catheter; to have 2 peritoneal catheter outlets from one shunt or to have two ventricular catheter inlets to one shunt.



DRAINAGE SYSTEMS*

- Drainage System Types

A) EXTERNAL VENTRICULAR DRAINAGE SYSTEM (ENDS AND EVD CATHETER KIT)

B) EXTERNAL LUMBAR DRAINAGE SYSTEM (ENDS AND LUMBAR DRAINAGE CATHETER KIT)

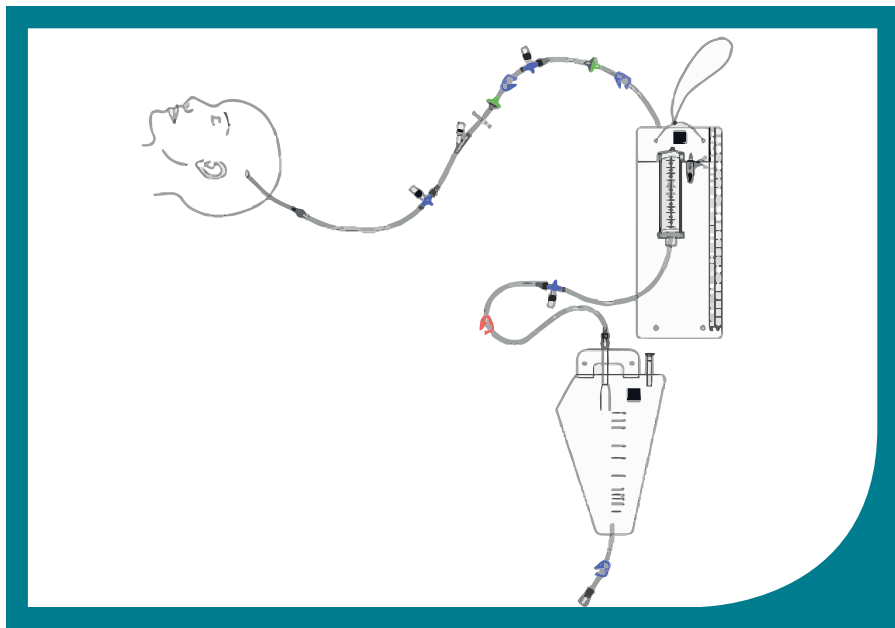
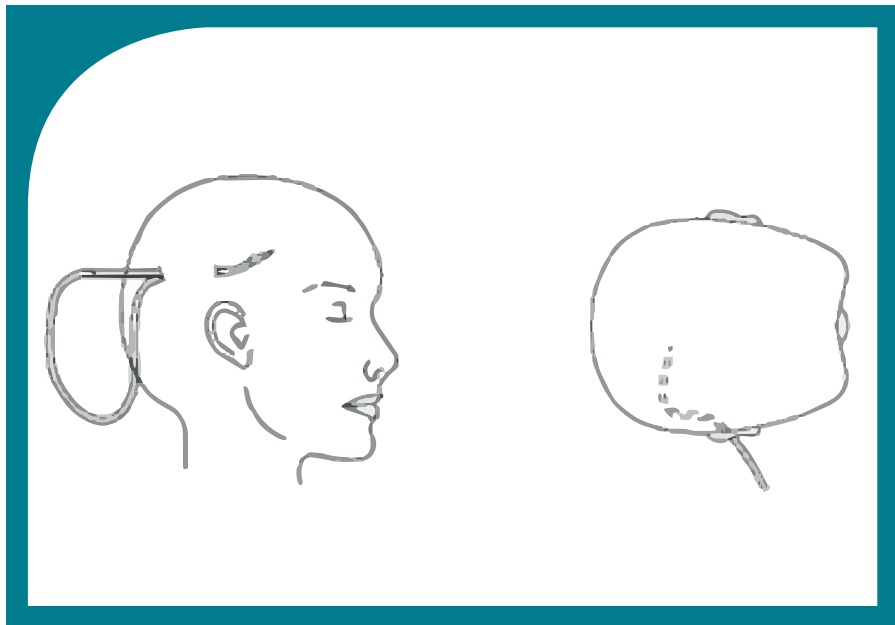
* All drainage systems are supplied sterile (method: EO-Ethylene Oxide).



Drainage System Types

A) EXTERNAL VENTRICULAR DRAINAGE SYSTEM (ENDS AND EVD CATHETER KIT)

DESU® External Ventricular Drainage System consists of 1 ENDS (External Neurological Drainage System) and 1 External Ventricular Drainage Catheter kit. The External Ventricular Drainage System is used when use of permanent shunt implant is not necessary or suitable to reduce the intra-cranial pressure by means of CSF drainage. The system is available with 2 options: with a standard EVD catheter kit or an antibiotic impregnated EVD catheter kit.

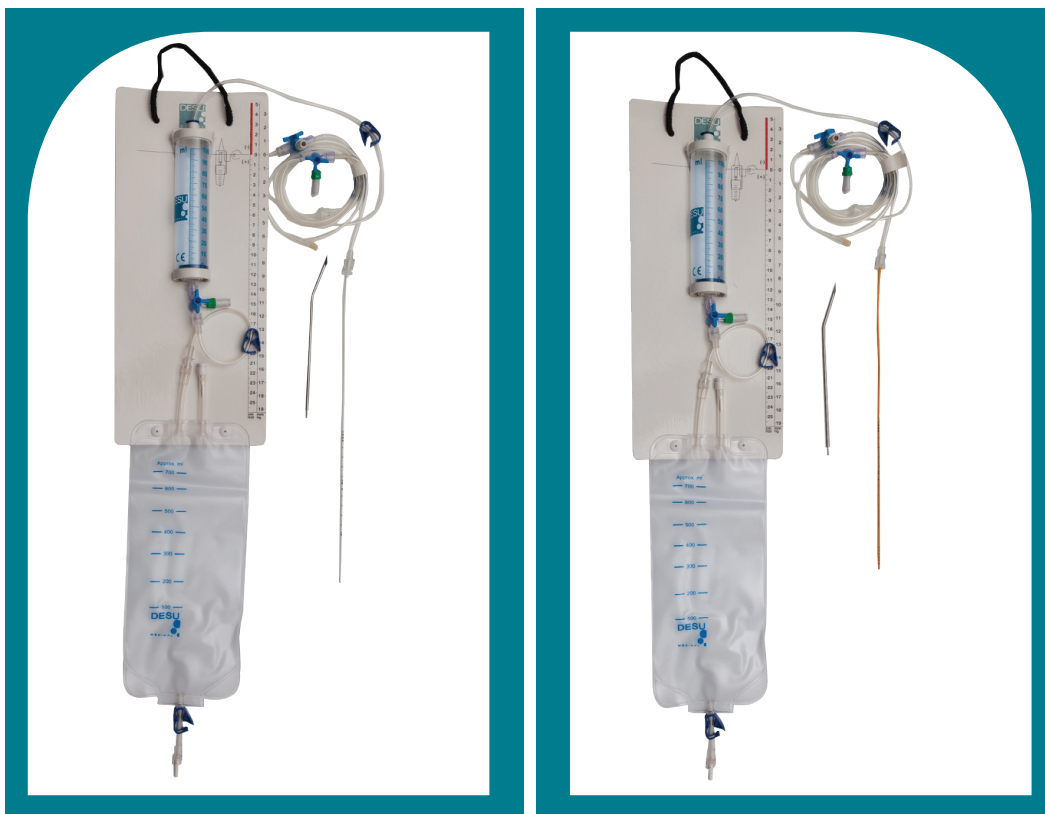


ENDS (External Neurological Drainage System) consists of the following parts:

- 1, female luer connector and luer cap (to connect the catheter to the distal outlet)
- 1, 60 cm reinforced rope with locking mechanism
- 1, 30 cm measurement scale (to adjust the CSF level according to mm Hg level)
- 1, 100 ml drip chamber with anti-microbial filter
- 1, 250 cm patient line that consists of: 1 male luer connector with cap, 3 three-way connectors, 1 y-connector with injection port, 4 clamps
- 1, 700 ml sterile drainage bag that has: an air filter, 1 outlet and level indicators at every 100 ml and has an air-filter
- 1 ventricular (standard/antibiotic impregnated) or lumbar drainage catheter (standard), according to intended use

EVD (External Ventricular Drainage) Catheter kit consists of the following parts:

- 1 External Ventricular Drainage Catheter
- 1, 32 cm stainless steel stylet (for insertion of the catheter)
- 1, stainless steel trocar needle with bended tip to allow catheter passage under the skin during catheterization
- 1 luer connector
- 1 silicone fixation tab



B) EXTERNAL LUMBAR DRAINAGE SYSTEM (ENDS AND LUMBAR DRAINAGE CATHETER KIT)

DESU® External Lumbar Drainage System consists of 1 ENDS (External Neurological Drainage System) and 1 External Lumbar Drainage Catheter kit. The External Lumbar Drainage System is used when use of permanent shunt implant is not necessary or suitable to reduce the CSF pressure by means of CSF drainage through the subarachnoid cavity.

ENDS (External Neurological Drainage System) consists of the following parts:

- 1, female luer connector and luer cap (to connect the catheter to the distal outlet)
- 1, 60 cm reinforced rope with locking mechanism
- 1, 30 cm measurement scale (to adjust the CSF level according to mm Hg level)
- 1, 100 ml drip chamber with anti-microbial filter
- 1, 250 cm patient line that consists of: 1 male luer connector with cap, 3 three-way connectors, 1 y-connector with injection port, 4 clamps
- 1, 700 ml sterile drainage bag that has: an air filter, 1 outlet and level indicators at every 100 ml and has an air-filter
- 1 ventricular (standard/antibiotic impregnated) or lumbar drainage catheter (standard), according to intended use

External Lumbar Drainage Catheter kit consists of the following parts:

- 1 External Lumbar Drainage Catheter
- 1, stainless steel trocar needle with bended tip to allow catheter passage under the skin during catheterization
- 1 luer connector
- 1 silicone fixation tab



COLLAGEN BASED IMPLANT SYSTEMS

COLLAGEN BASED IMPLANT SYSTEMS

A) DECOLL COLLAGEN BASED DURAL GRAFT

B) DEBONE COLLAGEN BASED BONE GRAFT



COLLAGEN BASED IMPLANT SYSTEMS

A) DECOLL COLLAGEN BASED DURAL GRAFT

DECOLL graft is used for the repair of dura mater defects and is manufactured using the purest source of collagen in the market, which is bovine collagen.

DECOLL is supplied in sponge form and sterilized using Gamma irradiation.

Currently available sizes of DECOLL are as follows:

Sizes	
2,5 cm x 2,5 cm	10 cm x 10 cm
5 cm x 5 cm	10 cm x 12,5 cm
6 cm x 6 cm	12,5 cm x 12,5 cm
7.5 cm x 7.5 cm	12,5 cm x 15 cm
8 cm x 8 cm	15 cm x 15 cm



B) DEBONE COLLAGEN BASED BONE GRAFT

DEBONE graft is used to decrease the healing time and enhance the repair process of bone defects mainly in the spinal area but can also be used in other areas of the body as well. DECOLL is manufactured using the purest source of collagen in the market, which is bovine collagen. DECOLL is supplied in both sponge form granules form and sterilized using Gamma irradiation.

Currently available sizes of sponge form DECOLL are as follows:

Sizes	
2,5 cm x 2,5 cm	10 cm x 10 cm
5 cm x 5 cm	10 cm x 12,5 cm
6 cm x 6 cm	12,5 cm x 12,5 cm
7.5 cm x 7.5 cm	12,5 cm x 15 cm
8 cm x 8 cm	15 cm x 15 cm



Currently available sizes of granule form DECOLL are as follows:

Sizes
5 cc
10 cc
15 cc
20 cc
25 cc
30 cc



QUALITY CERTIFICATES

TSE
TÜRK STANDARLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION
AT TASARIM İNCELEME BELGESİ
(EC DESIGN EXAMINATION CERTIFICATE)
BELGE NO (CERTIFICATE NO): 1783-MDD-008

Aşağıdaki ve adresi ya da üreticisi:
(Design of the manufacturer)
DESU MEDİKAL ÜRÜNLER VE TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.

UNİVERSİTELER MAHALLESİ 1596. CADDE SAĞIR BLOKLARI E BLOK OFİS NO: 02/03 ZEMİN KAT KAPİ NO: 6
BEYTEPE-ÇANKAYA-ANKARA/TÜRKİYE (Market Address/Head Office)
UNİVERSİTELER MAHALLESİ 1596. CADDE SAĞIR BLOKLARI E BLOK OFİS NO: 02/03 ZEMİN KAT KAPİ NO: 6
BEYTEPE-ÇANKAYA-ANKARA/TÜRKİYE (E-mail: Yeni@desu.com.tr)

93/42/AT - Tıbbi Cihaz Yönetmeliği (EK-II Madde 4) kapsamında güncel olarak ve belgelenmiştir.
(Has been examined and certified according to 93/42/EEC Medical Device Directive (ANNEX II Article 4))

- HİDROSEFAL SİLİKON SANTİSİSTEMLERİNİN (HİDROSEFAL SİLİKON BASINÇ SİSTEMİ, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
- HİDROSEFAL POLİSİLİKON SİSİTEMLERİNİN (HİDROSEFAL POLİSİLİKON SİSTEMİ, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
- HİDROSEFAL SİLİKON KATETERLERİNİN (HİDROSEFAL SİLİKON KATETER, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
- HİDROSEFAL SİLİKON KATETERLERİNİN (HİDROSEFAL SİLİKON KATETER, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
- HİDROSEFAL SİLİKON KATETERLERİNİN (HİDROSEFAL SİLİKON KATETER, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
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Onaylanma Kuruluş No/Notified Body Number: 1783
Belge Veriliş Tarihi/First Issue: 08.01.2014
Belge Geçerlilik Tarihi/Valid Until: 08.01.2019
Proje Kayıt No/Project Registration Number: 527-13/27861-27891
GMDN Kodu/GMDN Code: 16244 Şant Sistem, 32583 Kateter, 36151 Eksternal Nörolojik Drainaj Sistemi
Tam Kalite Güvence Belgesi No: 1783-MDD-008
Number Certificate Of Full Quality Assurance Module: 1783-MDD-008
Tasarım Değerlendirme Rapor No: 527-MDD-008-2013-04 & 527-MDD-008-2014-04 & 527-MDD-008-2016-01
Design Dossier Review Report Number: 527-MDD-008-2016-01
Belge Değişiklik Tarihi/ Nedeni: 13/05/2016 / Adres Değişikliği
Date / Reason of the Certificate Revision: 13/05/2016 / Address Change

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TURKISH STANDARDS INSTITUTION
CERTIFICATE OF FULL QUALITY ASSURANCE

DESU MEDİKAL ÜRÜNLER VE TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.
(Design of the manufacturer)
UNİVERSİTELER MAHALLESİ 1596. CADDE SAĞIR BLOKLARI E BLOK OFİS NO: 02/03 ZEMİN KAT KAPİ NO: 6 BEYTEPE-ÇANKAYA-ANKARA/TÜRKİYE
for the scope of:

- HİDROSEFAL SİLİKON SİSİTEMLERİNİN (HİDROSEFAL SİLİKON BASINÇ SİSTEMİ, TİKKİLENDİRİLMİŞ/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI/ANTİBİYOTİK EMİRLİMİŞ) (STANDARD/ANTİBİYOTİK EMİRLİMİŞ VE AKSESUARLI (ANTİSPHON) SİSTEMİ) (LOW/MEDIUM/HIGH PRESSURE, STERILE, SINGLE USE) (STANDARD/ANTIBIOTIC IMPREGNATED) AND ACCESSORY (ANTISPHON) SYSTEMS)
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has been examined and certified to the requirements of
93/42/EEC – Medical Device Directive Full Quality Assurance Module – Module H (Annex-II Article 4 Excluded)
by considering the related clauses of TS EN ISO 13485:2012

Notified Body Number: 1783
Certificate Issue Date: 08.01.2014
Valid Until: 08.01.2019
GMDN Code: 16244 Şant Sistem, 32583 Kateter, 36151 Eksternal Nörolojik Drainaj Sistemi
EC Design Examination Certificate Number: 1783-MDD-008
Examination Report Number: 527-MDD-008-2013-04 & 527-MDD-008-2014-04 & 527-MDD-008-2016-01

Date / Reason of the Certificate Revision: 13/05/2016 / Address Change
This certificate remarks that quality system meets requirements of the technical regulations / harmonized standards and with this certificate the company is authorized to affix CE Mark, as shown below, and Notified Body Number on the products in the scope of the examined quality system. Notified Body has the right to carry out surveillance visits announced or unannounced in accordance with section 5 of Annex 2 of Medical Device Directive.
For CE marking the class III devices covered by this certificate, an EC design-examination certificate according to MDD Annex II (c) is also required.

CE Certificate Number: 1783-MDD-009
Seza DOĞAN
Direktör Yardımcısı
ANKARA Rev.02, 13.05.2016

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bsi. 
By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that: **DESU MEDİKAL ÜRÜNLERİ ve TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.**
Universiteler Mah. 1596. Cad
Sağır Blokları E Blok, Ofis No: 02/03
Zemin Kat Kapı No: 6
Beytepe Çankaya
Ankara
Türkiye

Holds Certificate Number: MD 622854
and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:
The design, manufacture, sales of sterile shunts, catheters, drainage systems and sterile bovine collagen implants used for cranial and spinal repair.

For and on behalf of BSI: Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 11/05/2016 Effective Date: 11/05/2016
Latest Revision Date: 11/05/2016 Expiry Date: 28/02/2019

Page: 1 of 1
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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated via www.bsi.org.uk/CertificateDirectory
Information and Contact: BSI, 9000 Market Road, Bournemouth, Dorset, BH8 8RS, UK. Tel: +44 (0)1203 690900
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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TÜRK STANDARLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION
TAM KALİTE GÜVENCE BELGESİ

DESU MEDİKAL ÜRÜNLER VE TIBBİ CİHAZLAR SAN. VE TİC. A.Ş.
(Design of the manufacturer)
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has been examined and certified to the requirements of
93/42/AT – Tıbbi Cihaz Yönetmeliği Tam Kalite Güvence Modülü – Modül H (EK-II Madde 4 Hariç)
in accordance with the requirements of TS EN ISO 13485:2012 in light of the related clauses of the technical regulations and the requirements of the scope of the examined quality system.

Onaylanma Kuruluş Numarası: 1783
Belge Veriliş Tarihi: 08.01.2014
Geçerlilik Tarihi: 08.01.2019
GMDN Kodu: 16244 Şant Sistem, 32583 Kateter, 36151 Eksternal Nörolojik Drainaj Sistemi
AT Tasarım İnceleme Belgesi Numarası: 1783-MDD-008
İnceleme Rapor Numarası: 527-MDD-008-2013-04 & 527-MDD-008-2014-04 & 527-MDD-008-2016-01
Belge Değişiklik Tarihi/ Nedeni: 13/05/2016 / Adres Değişikliği

Kalite Sisteminin Teknik Düzenleme / Uyumluluğunun Standart gereklilikleri karşıladığını gösteren, işbu belge ile Kuruluşun, belirli yönetim kalite sistemi kapsamında CE İşaretiyle İşaretleme, satışta gösterildiği şekilde işletmeye ve Onaylanma Kuruluşu tarafından kullanılmasına ilişkin olarak Onaylanma Kuruluşu Tıbbi Cihaz Yönetmeliğinin EK-2, 5. kısımda istenilen planlı plan dışı güncellemeleri yapma hakkına sahiptir. Bu belge kapsamında bulunan Sınıfl III ürün için CE İşaretleme için, Tıbbi Cihaz Yönetmeliği EK-2, 4. kısımda diğer düzenlemeler Tasarım İnceleme Belgesi ile gereklidir.

CE Belge No: 1783-MDD-009
Seza DOĞAN
Direktör Yardımcısı
ANKARA Rev.02, 13.05.2016

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R & D and Production Facility

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