



POLY MEDICURE LIMITED

TECHNICAL DATA SHEET

Huber Infusion Set with/without Safety Features

S. No.	Variants Configurations	Product Code
1.	Safety Huber Infusion Set-19G x 25mm	95001
2.	Safety Huber Infusion Set-19G x 19mm	95002
3.	Safety Huber Infusion Set-20G x 25mm	95003
4.	Safety Huber Infusion Set-20G x 19mm	95004
5.	Safety Huber Infusion Set-20G x 32mm	95005
6.	Safety Huber Infusion Set-22G x 25mm	95006
7.	Safety Huber Infusion Set-22G x 19mm	95007
8.	Safety Huber Infusion Set-22G x 32mm	95008
9.	Safety Huber Infusion Set-19G x 16mm	95110
10.	Safety Huber Infusion Set -19G x 32mm	95111
11.	Safety Huber Infusion Set -19G x 38mm	95112
12.	Safety Huber Infusion Set -20G x 16mm	95113
13.	Safety Huber Infusion Set -22G x 16mm	95114
14.	Safety Huber Infusion Set -19G x 16mm, with NFC	95115
15.	Safety Huber Infusion Set -19G x 19mm with NFC	95116
16.	Safety Huber Infusion Set -19G x 25mm with NFC	95117
17.	Safety Huber Infusion Set -19G x 32mm with NFC	95118
18.	Safety Huber Infusion Set -19G x 38mm with NFC	95119
19.	Safety Huber Infusion Set -20G x 16mm with NFC	95120
20.	Safety Huber Infusion Set -20G x 19mm with NFC	95121
21.	Safety Huber Infusion Set -20G x 25mm with NFC	95122
22.	Safety Huber Infusion Set -20G x 32mm with NFC	95123
23.	Safety Huber Infusion Set -22G x 16mm with NFC	95124
24.	Safety Huber Infusion Set -22G x 19mm with NFC	95125
25.	Safety Huber Infusion Set -22G x 25mm with NFC	95126
26.	Safety Huber Infusion Set -22G x 32mm with NFC	95127
27.	Safety Huber Infusion Set-20G x 17mm	95130
28.	Safety Huber Infusion Set-20G x 20mm	95131
29.	Safety Huber Infusion Set-20G x 30mm	95132
30.	Safety Huber Infusion Set-20G x 35mm	95133
31.	Safety Huber Infusion Set-22G x 17mm	95134
32.	Safety Huber Infusion Set-22G x 20mm	95135
33.	Safety Huber Infusion Set with NFC-20G x 17mm	95136
34.	Safety Huber Infusion Set with NFC-20G x 20mm	95137
35.	Safety Huber Infusion Set with NFC-20G x 30mm	95138
36.	Safety Huber Infusion Set with NFC-20G x 35mm	95139
37.	Safety Huber Infusion Set with NFC-22G x 17mm	95140
38.	Safety Huber Infusion Set with NFC-22G x 20mm	95141
39.	Safety Huber Infusion Set with NFC-20G x 38mm	90701
40.	Safety Huber Infusion Set with NFC-22G x 38mm	90702
41.	Safety Huber Infusion Set with NFC-19G x 12.7mm	90703
42.	Safety Huber Infusion Set with NFC-20G x 12.7mm	90704

S. No.	Variants Configurations	Product Code
43.	Safety Huber Infusion Set with NFC-22G x 12.7mm	90705
44.	Safety Huber Infusion Set-19G x 12.7mm	90706
45.	Safety Huber Infusion Set-20G x 12.7mm	90707
46.	Safety Huber Infusion Set-22G x 12.7mm	90708
47.	Safety Huber Infusion Set-20G x 38mm	90709
48.	Safety Huber Infusion Set-22G x 38mm	95129
49.	Safety Huber Infusion Set-19G x 16mm with Y- Site	95142
50.	Safety Huber Infusion Set-19G x 19mm with Y- Site	95143
51.	Safety Huber Infusion Set-19G x 25mm with Y- Site	95144
52.	Safety Huber Infusion Set-19G x 32mm with Y- Site	95145
53.	Safety Huber Infusion Set-19G x 38mm with Y- Site	95146
54.	Safety Huber Infusion Set-20G x 16mm with Y- Site	95147
55.	Safety Huber Infusion Set-20G x 19mm with Y- Site	95148
56.	Safety Huber Infusion Set-20G x 25mm with Y- Site	95149
57.	Safety Huber Infusion Set-20G x 32mm with Y- Site	95150
58.	Safety Huber Infusion Set-20G x 38mm with Y- Site	95151
59.	Safety Huber Infusion Set-22G x 16mm with Y- Site	95152
60.	Safety Huber Infusion Set-22G x 19mm with Y- Site	95153
61.	Safety Huber Infusion Set-22G x 25mm with Y- Site	95154
62.	Safety Huber Infusion Set-22G x 32mm with Y- Site	95155
63.	Safety Huber Infusion Set-22G x 38mm with Y- Site	95156
64.	Safety Huber Infusion Set with Y- Site-19G x 12.7mm	95157
65.	Safety Huber Infusion Set with Y- Site-20G x 12.7mm	95158
66.	Safety Huber Infusion Set with Y- Site-22G x 12.7mm	95159
67.	Huber Infusion Set-19G x 16mm with Y-site	95010
68.	Huber Infusion Set -19G x 19mm with Y-site	95011
69.	Huber Infusion Set -19G x 25mm with Y-site	95012
70.	Huber Infusion Set -19G x 32mm with Y-site	95013
71.	Huber Infusion Set -19G x 38mm with Y-site	95014
72.	Huber Infusion Set -20G x 16mm with Y-site	95015
73.	Huber Infusion Set -20G x 19mm with Y-site	95016
74.	Huber Infusion Set -20G x 25mm with Y-site	95017
75.	Huber Infusion Set -20G x 32mm with Y-site	95018
76.	Huber Infusion Set -22G x 16mm with Y-site	95019
77.	Huber Infusion Set -22G x 19mm with Y-site	95020
78.	Huber Infusion Set -22G x 25mm with Y-site	95021
79.	Huber Infusion Set-20G x 38mm	90710
80.	Huber Infusion Set-22G x 32mm	90711
81.	Huber Infusion Set-22G x 38mm	90712
82.	Huber Infusion Set with Y- Site-20G x 38mm	90713
83.	Huber Infusion Set with Y- Site-22G x 32mm	90714
84.	Huber Infusion Set with Y- Site-22G x 38mm	90715

S. No.	Variants Configurations	Product Code
85.	Huber Infusion Set with NFC-20G x 38mm	90716
86.	Huber Infusion Set with NFC-22G x 32mm	90717
87.	Huber Infusion Set with NFC-22G x 38mm	90718
88.	Huber Infusion Set -19G with 16mm	95035
89.	Huber Infusion Set -19G with 19mm	95036
90.	Huber Infusion Set -19G with 25mm	95037
91.	Huber Infusion Set 19G with 32mm	95038
92.	Huber Infusion Set -19G with 38mm	95039
93.	Huber Infusion Set -20G with 16mm	95040
94.	Huber Infusion Set -20G with 19mm	95041
95.	Huber Infusion Set -20G with 25mm	95042
96.	Huber Infusion Set -20G with 32mm	95043
97.	Huber Infusion Set -22G with 16mm	95044
98.	Huber Infusion Set -22G with 19mm	95045
99.	Huber Infusion Set -22G with 25mm	95046
100.	Huber Infusion Set -19G x16mm with NFC	95047
101.	Huber Infusion Set -19Gx19mm with NFC	95048
102.	Huber Infusion Set -19Gx25mm with NFC	95049
103.	Huber Infusion Set -19Gx32mm with NFC	90531
104.	Huber Infusion Set -19Gx38mm with NFC	90532
105.	Huber Infusion Set -20Gx16mm with NFC	90533
106.	Huber Infusion Set -20Gx19mm with NFC	90534
107.	Huber Infusion Set -20Gx25mm with NFC	90535
108.	Huber Infusion Set -20Gx32mm with NFC	90536
109.	Huber Infusion Set -22Gx16mm with NFC	90537
110.	Huber Infusion Set -22Gx19mm with NFC	90538
111.	Huber Infusion Set -22Gx25mm with NFC	90539
112.	Huber Infusion Set-20G x 30mm	90550
113.	Huber Infusion Set-20G x 35mm	90551
114.	Huber Infusion Set-22G x 17mm	90552
115.	Huber Infusion Set-22G x 20mm	90553
116.	Huber Infusion Set with NFC-20G x 17mm	90554
117.	Huber Infusion Set with NFC-20G x 20mm	90555
118.	Huber Infusion Set with NFC-20G x 30mm	90556
119.	Huber Infusion Set with NFC-20G x 35mm	90557
120.	Huber Infusion Set with NFC-22G x 17mm	90558
121.	Huber Infusion Set with NFC-22G x 20mm	90559

Product Images



Huber Infusion Set with & without Safety



Huber Infusion Set with Y-Site

Huber Infusion Set with NFC

General Information:

Intended Use

Huber Infusion set with/without safety is a device intended for insertion into the septum of implanted ports and infusion of fluids into the port.

Legal Manufacturer-

POLY MEDICURE LIMITED

Plot No.: 115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA – 121004

POLY MEDICURE LIMITED

Plot No.: 33-34, Sector 68, IMT,
Faridabad- 121004, Haryana, INDIA



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Manufacturing Site-

POLY MEDICURE LIMITED

Plot No.: 115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh,
Faridabad, HARYANA, INDIA – 121004

POLY MEDICURE LIMITED

Plot No.: 33-34, Sector 68, IMT,
Faridabad- 121004, Haryana, INDIA

European Authorized Representative- Name and address

OBELIS S.A.

Boulevard Général Wahis 53,
B-1030, Brussels,
Belgium

Certification:

Manufacturing Site	Certification	Notified Body
Plot No.:115, 116 & 117, Sector 59, HSIIDC Industrial Area, Ballabhgarh, Faridabad, Haryana, INDIA – 121004	CE Certificate Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III <u>CE Certificate No.: G10 105484 0003</u>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany <u>Notified Body Number: 0123</u>
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 041938 0001</u>	
POLY MEDICURE LIMITED Plot No.: 34, Sector 68, IMT, Faridabad- 121004, Haryana, INDIA	CE Certificate Medical Device Directives 93/42/EEC- Annex II <u>CE Certificate No.: G1 105485 0007 (CL 105485 0010)</u>	
	EN ISO 13485:2016/DIN-EN ISO 13485:2016 <u>Certificate No.: Q5 105485 0006</u>	

Device Classification:

- As per "Classification Criteria" in Annexure- VIII of EU Regulation 2017/745, Huber Infusion Sets are normally intended for continuous use for between 60 minutes and 30 days. Hence, these are for short-term device as per description in 1.2 of Annexure- VIII.
- As Huber Infusion Set is an external communicating device that penetrate inside the body through the surface of the body, hence is "Invasive device" as per 2.2 of Annexure VIII.
- As per Rule- 7 for Classification, all 'surgically invasive devices' intended for short-term use are classified in Class IIa. Hence Huber Infusion Set with/without safety are classified as Class- IIa Medical device.

Device Description:

Huber infusion sets are suitable for injecting the medication through implanted port or withdrawal of blood from the Y-Injection port with a simple luer connection. The product is provided with safety feature to prevent accidental needle prick injury. Huber Infusion Sets are an alternative to other infusion delivery systems. They are used in conjunction with patient implanted ports and are used for patient therapies requiring repeated vascular access and long-term fluid therapies.

A Huber needle is a specially designed hollow needle used with a chemotherapy port. The needle has a long, beveled tip that can go through skin as well as the silicone septum of the implanted port's reservoir. Huber needles are used to administer chemotherapy, antibiotics, and total parental nutrient (TPN) through an implanted IV port. These needles may be left in the port for many days at a time. A Huber Infusion Set with Safety feature (Safety Huber Needle) retracts or shields the needle upon removal from the implanted port preventing the potential of recoil resulting in an accidental needle stick. These needles can be used during infusion to give chemotherapy drugs, antibiotics or saline fluid. The major advantage of using a Huber infusion set is its potential to reduce the risk of infections in critically ill patients.

Huber needles come in several lengths and gauges. User should know the size of needle that works with the port. If users use a Huber needle that is too short, it won't work well for blood drawing or infusion. If a Huber is too short, it may feel painful and tight. Likewise, a Huber needle that is too long for port might wobble or spin around, causing damage to the silicone seal.

Technical Specification:

- The 90° curved Huber Needle helps for perpendicular insertion into silicon septum of the implanted port, ensuring direct, reliable access. This orientation minimizes the chance of needle shifting or dislodgement caused by patient movement.*
- The non-coring needle design maximizes the implantable port septum life by piercing the silicone septum without removing /damaging the septum material.*
- Huber Infusion Set with safety features ensures user or patient safety as the safety mechanism locks the needle in the safety position after withdrawal of needle and prevent accidental Needle Prick Injuries.*
- The tubing is made up of Polyurethane material, which is ideal for chemotherapy applications.*
- Variants available with Y Injection Site or Needle free Y-site for providing intermediate medication.*
- Color coded Huber Base identifies needle gauge and facilitate secure fixation of the needle in port septum; for safety variant the Huber base accommodates the safety mechanism, soft wings, etc.*
- Huber Infusion Set variants which are sustainable to Power injection up to 325Psi are also available.*
- Ergonomically designed soft wings with serrations/textures offers better grip while using with gloves and facilitate secure fixation.*
- 6% tapered luer connection as per EN ISO 80369-7:2021 is provided for leak proof connection with other connecting parts or devices and ensures adequate engagement.*

- Device is available in different needle lengths, i.e., 12.7mm, 16mm, 17mm, 19mm, 20mm, 25mm, 30mm, 32mm, 35mm and 38mm.
- Device is color coded for needle size identification, i.e., for needle sizes 19G, 20G, 22G, the huber base and wing are color coded as brown, yellow, black respectively.
- Huber Infusion Set without NFC and without Y-site is compatible with power injectors up to 325 PSI. Huber Infusion Set with NFC and Y-site is NOT compatible with power injectors.

Specifications for Power Injector variants:

Product Code	Product Variant	Maximum Flow Rate (ml/s) for Contrast Media Viscosity 12 cP@37°C	Maximum Static Burst Pressure sustainability, greater than 325psi
95006-95008, 95134-95135, 95114, 90708, 95129	Safety Huber Infusion Set - 22G	2.0ml/sec.	Complies
95003-95005, 95130-95133, 95113, 90707, 90709	Safety Huber Infusion Set - 20G	5.0ml/sec.	Complies
95001-95002, 95110-95112, 90706	Safety Huber Infusion Set - 19G	5.0ml/sec.	Complies
90711-90712, 95044-95046, 90552-90553	Standard Huber Infusion Set - 22G	2.0ml/sec.	Complies
90550-90551, 95040-95043, 90710,	Standard Huber Infusion Set - 20G	5.0ml/sec.	Complies
95035-95039	Standard Huber Infusion Set - 19G	5.0ml/sec.	Complies

Approved Materials of Constructions:

S. No.	Parts Where Material is used	Base Material	CAS No.
1.	Huber Base	ABS	9003-56-9
2.	Needle Hub (safety)	PA	25038-74-8
3.	Needle Hub (Non-safety)	PVC	9002-86-2
4.	Wing	PVC	9002-86-2
5.	Safety wire	Nitinol	52013-44-2
6.	Needle	SS	65997-19-5
7.	Tube	PU	550-33-4
8.	Tube Clamp	PA	9002-81-7
9.	Straight Luer	PC	25037-45-0

S. No.	Parts Where Material is used	Base Material	CAS No.
10.	Luer Lock	HDPE	9002-88-4
11.	Y-Connector without Latex	ABS	9003-56-9
12.	Reducer Connector	ABS	9003-56-9
13.	Needle Free Y Connector	PC + Silicone	25037-45 + 63394-02-5
14.	Needle Cover	FEP/LDPE	25067-11-2
15.	Foam	PE Foam with Adhesive	9002-88-4
16.	Needle hub Cover	PC	

Sterilization Method:

Sterilized using Ethylene Oxide

Shelf Life:

Five years from the date of manufacturing

Standards Compliance:

Document Code	Document Description
<i>EU MDR 2017/745</i>	<i>European Medical Device Regulation 2017/745</i>
<i>EN ISO 13485:2016+ A11:2021</i>	<i>Quality system - Medical Devices - Requirements for the Regulatory Purposes</i>
<i>EN ISO 14971:2019/ A11:2021</i>	<i>Application of risk management to medical devices</i>
<i>IEC 62366-1:2015 / Amd 1:2020</i>	<i>Medical Devices – Application of usability engineering to medical devices</i>
<i>EN ISO 11135:2014 /A1:2019</i>	<i>Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.</i>
<i>EN ISO 11737-1:2018/A1:2021</i>	<i>Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.</i>
<i>EN ISO 11737-2:2020</i>	<i>Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.</i>
<i>EN ISO 11607-1:2020/ A1:2023</i>	<i>Packaging for terminally sterilized medical devices – requirements for materials, sterile barrier & packaging systems.</i>
<i>EN ISO 11607-2:2020/ A1:2023</i>	<i>Packaging for terminally sterilized medical devices – Validation requirements for forming, sealing and assembly process.</i>
<i>EN ISO 15223-1:2021</i>	<i>Symbols to be used with medical devices labels, labeling and information to be supplies</i>



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Document Code	Document Description
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices – Evaluation and testing within a risk management process.
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
EN ISO 14644-1:2015	Clean rooms and associated controlled environments – Classification of air cleanliness

Reference to QMDS Documents:

Document Title	Polymed Internal Document Reference
Technical File	PML/MD/TF/45
Product Specification	FP/QA/73
Risk Management	PML/MD/RA/45
Clinical Evaluation	PML/MD/CER/45
DOC	F/QA/176

Packaging Characteristics:

Unit Pack		Duplex Pack		Carton Pack	
Size (mm)	Qty.	Size L x W x H (mm)	Qty.	Size L x W x H (mm)	Qty.
128 x 78	1 No.	160 x 132 x 132	20 Nos.	685 x 275 x 185	200 Nos.

Storage Conditions:

Store in between 5°C to 35°C, avoid excessive heat, protect from direct sunlight and moisture.

Materials of Concern:

- Not made with natural rubber latex or DEHP plasticizer.
- Any substances of animal origin e.g., BSE/TSE are not used during manufacturing.