

# GRIPPER PLUS® Safety Huber Needles

## Technical Summary

### DEVICE CLASSIFICATION

#### US Classification

Class II/§880.5440

#### Canada Classification

Class II, Rule 1

#### Australia Classification

Class IIa, Rule 3.2

#### EU Classification

Class IIa, Rule 7

### DEVICE DESCRIPTION

This device is intended for single use only and is provided sterile and non-pyrogenic. The materials used to manufacture this device do not contain latex and are DEHP-free. This is an Rx Device.

#### GMDN

17180

#### CE MARK NUMBER

0086

### INDICATIONS

This product is indicated for the administration into, or withdrawal of fluids from implanted ports. It is designed to help protect against exposure to bloodborne pathogens caused by accidental needle stick injuries. It does not protect against other routes of bloodborne pathogen transmission.

### LEGAL MANUFACTURER

Smiths Medical ASD, Inc.  
6000 Nathan Lane North  
Minneapolis, MN 55442 USA

### MANUFACTURING SITE NAME AND ADDRESS

Smiths Healthcare Manufacturing S.A.  
de C.V. Avenida Calidad No. 4  
Parque Industrial Internacional Tijuana  
Tijuana, B.C.C.P. Baja CA 22425 Mexico

### COUNTRY OF ORIGIN

Mexico

### ANIMAL ORIGIN

None of the devices listed on this product family incorporate any substances that are derived from animal tissues as per Commission Regulation (EU) 722/2012.

### STERILIZATION METHOD

Ethylene Oxide

### SHELF-LIFE

A 5-year expiration date is assigned to the product as long as the packaging is undamaged and unopened, based on accelerated aging stability shelf-life testing and real-time aging.

**Not manufactured with DEHP plasticizer**



### COMPONENT COMPOSITIONS

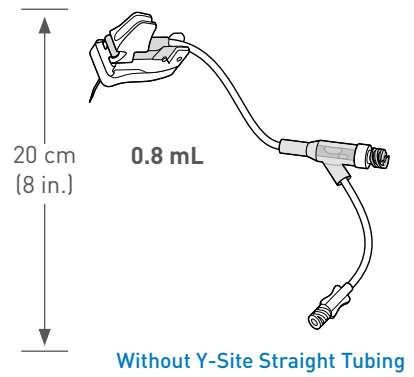
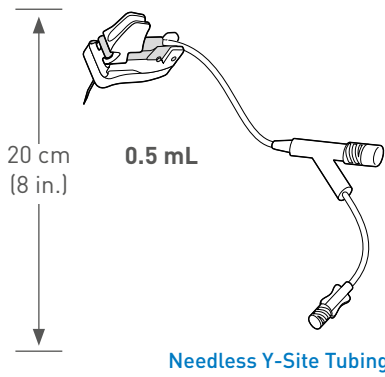
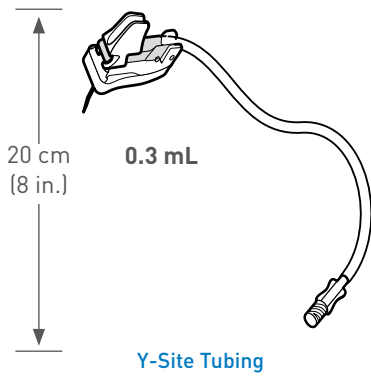
Clip	Acetal
Foam	EVA
Base & Pivot Arm	Acrylic Copolymer
Cannula	304 SS
Cannula Protector	LDPE
Tubing	PVC, TOTM
Clamp	Acetal
Female Luer	PVC, TOTM
Non-Vented Male Cap	Polypropylene

### LABELLING AND PACKAGING

Container Type	Length	Width	Height	Weight
Unit Pack (1 unit)	101 mm	145 mm	2.2 mm	13.6 g
Shelf Pack	205 mm	92 mm	148 mm	250 g
Case Pack	492 mm	422 mm	406 mm	7.4 kg

MR conditional up to 3 Tesla

## PRIMING VOLUME



## PRODUCT RANGE AND SPECIFICATIONS

### GRIPPER PLUS® Safety Huber Needles

Latex-free, non-coring, non-silicized, removable contoured grip, cushioned needle platform, 8" extension tubing with or without Y-site

Needleless Y-site – Luer-activated needleless injection site	Length	Reorder No.	UPC No.	Unit
22 gauge	16 mm (5/8 inch)	21-2960-24	(01) 3 0610586 02768 4	12/box
	19 mm (3/4 inch)	21-2961-24	(01) 3 0610586 02769 1	12/box
	25 mm (1 inch)	21-2962-24	(01) 3 0610586 02770 7	12/box
	32 mm (1 1/4 inch)	21-2963-24	(01) 3 0610586 02771 4	12/box
20 gauge	16 mm (5/8 inch)	21-2964-24	(01) 3 0610586 02772 1	12/box
	19 mm (3/4 inch)	21-2965-24	(01) 3 0610586 02773 8	12/box
	25 mm (1 inch)	21-2966-24	(01) 3 0610586 02774 5	12/box
	32 mm (1 1/4 inch)	21-2967-24	(01) 3 0610586 02775 2	12/box
19 gauge	19 mm (3/4 inch)	21-2968-24	(01) 3 0610586 02776 9	12/box
	25 mm (1 inch)	21-2969-24	(01) 3 0610586 02777 6	12/box
	32 mm (1 1/4 inch)	21-2970-24	(01) 3 0610586 02778 3	12/box
Y-site – Removable split septum injection cap on Luer-lock Y-site	Length	Reorder No.	UPC No.	Unit
22 gauge	16 mm (5/8 inch)	21-2860-24	(01) 3 0610586 02564 2	12/box
	19 mm (3/4 inch)	21-2861-24	(01) 3 0610586 02565 9	12/box
	25 mm (1 inch)	21-2862-24	(01) 3 0610586 02566 6	12/box
	32 mm (1 1/4 inch)	21-2863-24	(01) 3 0610586 02567 3	12/box
20 gauge	16 mm (5/8 inch)	21-2864-24	(01) 3 0610586 02568 0	12/box
	19 mm (3/4 inch)	21-2865-24	(01) 3 0610586 02569 7	12/box
	25 mm (1 inch)	21-2866-24	(01) 3 0610586 02570 3	12/box
	32 mm (1 1/4 inch)	21-2867-24	(01) 3 0610586 02571 0	12/box
19 gauge	19 mm (3/4 inch)	21-2868-24	(01) 3 0610586 02572 7	12/box
	25 mm (1 inch)	21-2869-24	(01) 3 0610586 02573 4	12/box
	32 mm (1 1/4 inch)	21-2870-24	(01) 3 0610586 02574 1	12/box
Without Y-site	Length	Reorder No.	UPC No.	Unit
22 gauge	16 mm (5/8 inch)	21-2770-24	(01) 3 0610586 02563 5	12/box
	19 mm (3/4 inch)	21-2766-24	(01) 3 0610586 02559 8	12/box
	25 mm (1 inch)	21-2760-24	(01) 3 0610586 02553 6	12/box
	32 mm (1 1/4 inch)	21-2761-24	(01) 3 0610586 02554 3	12/box
20 gauge	16 mm (5/8 inch)	21-2769-24	(01) 3 0610586 02562 8	12/box
	19 mm (3/4 inch)	21-2767-24	(01) 3 0610586 02560 4	12/box
	25 mm (1 inch)	21-2762-24	(01) 3 0610586 02555 0	12/box
	32 mm (1 1/4 inch)	21-2763-24	(01) 3 0610586 02556 7	12/box
19 gauge	19 mm (3/4 inch)	21-2768-24	(01) 3 0610586 02561 1	12/box
	25 mm (1 inch)	21-2764-24	(01) 3 0610586 02557 4	12/box
	32 mm (1 1/4 inch)	21-2765-24	(01) 3 0610586 02558 1	12/box

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

**Smiths Medical International Ltd**  
 1500 Eureka Park, Lower Pemberton  
 Ashford Kent, TN25 4BF  
 Tel: +44 (0)845 850 0445  
[www.smiths-medical.com](http://www.smiths-medical.com)

MMSPCA-0347



smiths medical

Smiths Medical is part of the global technology business Smiths Group plc. Please see the Instructions for Use/Operator's Manual for a complete listing of the indications, contraindications, warnings and precautions. Gripper Plus and the Smiths Medical design mark are trademarks Smiths Medical. The symbol © indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. ©2018 Smiths Medical. All rights reserved. VA192552GB-102018